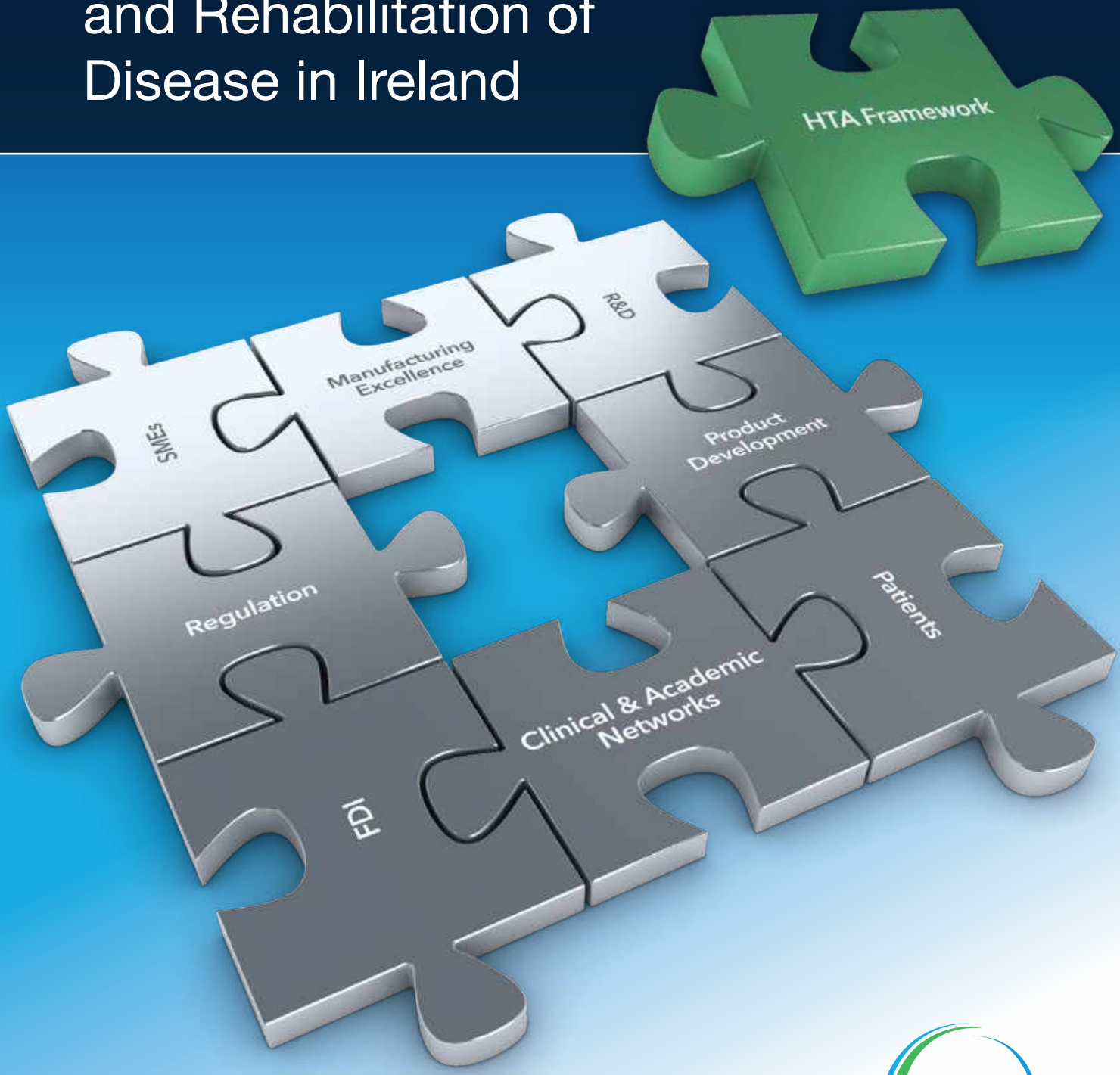
Assessing the Value of Medical Technologies in the Prevention, Diagnosis, Treatment and Rehabilitation of Disease in Ireland



IMSTA

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1. Executive Summary

This white paper proposes that a standardised approach for the evaluation of medical technologies for use in the public health system would optimally identify the most clinically useful and cost-effective technologies for the state to invest in. Such a system would also be of benefit to indigenous SMEs in validating the potential clinical cost benefit of the health products they are developing.

Ireland is recognised as a global hub for the manufacture and research of medical technologies with over 300 companies employing 29,000 people and 60% of companies carrying out valuable R&D activities (1). Despite the importance of the medtech[1] sector to the economy, Ireland as a country does not yet systematically evaluate and therefore fully adopt the innovative medtech products that may have been researched, developed and/or manufactured on the island. The valuable benefits to the patient, society and the economy are therefore potentially lost.

Similar to other global economies, Ireland's healthcare sector is facing increasing health care costs and growing patient needs due to ageing populations and the increased incidences of chronic illnesses. The medical technology industry plays a vital role in advancing efficiency and productivity within the health care system. Innovations in medical technology over the last two decades have dramatically altered the processes and methods by which medical care is provided (2). It is estimated that the Irish government spends over €500 million[2] per annum on medical technologies and therefore needs to know that patients are receiving best in class healthcare options leading to the best outcomes, that in turn are providing efficiencies to the healthcare system and value for money for the Irish taxpayer (3). However, without the implementation of a systematic evaluation process for medical technologies it is unlikely that this can or will be achieved.

The recently introduced Activity Based Funding system ("Money follows the patient") within hospitals could provide Ireland's healthcare system with the opportunity to correctly identify current costs, allocate budgets effectively and identify medical technologies that currently create value and better outcomes for patients. This not only delivers real economic value to the taxpayer but also demonstrates positive strides taken by the Irish government to adopt the most clinically and cost effective technologies and practices. Overall this can circle back positively into a large sector of the Irish economy that has continued to provide sustained growth in employment and a long-term strategy for success.

However, the current absence of a standardised evaluation process means medical technologies cannot today be systematically assessed and therefore we run the risk of not realising the true value of medtech in the overall treatment of disease and of obtaining sub-optimal outcomes for patients and the health system.

Not all medical devices or technologies being placed on the market in Ireland would need to be subjected to a rigorous HTA[3], on a par with HTAs currently being undertaken for new medicines. Only step change, innovative or high cost technologies with very significant national budgetary impact would need to undergo the most rigorous HTA-type evaluation process. Less complex technologies could be assessed using simpler evaluation methodologies, such as mini-HTAs, which could be undertaken regionally by, for example, hospital groups or other appropriate academic / clinical research institutions. All other medical devices / technologies could be put through a standardised value-based procurement process, including all health products listed under the Primary Care Reimbursement System (PCRS). So, while there could be one National HTA Strategy for the evaluation of medical devices / technologies, the appropriate assessments could be carried out nationally, regionally or locally.

1 'medtech' refers to medical technologies which encompass a wide range of healthcare products used to diagnose, monitor or treat diseases or medical conditions affecting humans

2 Health Service Executive Annual Report and Financial Statements 2010 - 2015

3 A Health Technology Assessment (HTA) is a systematic evaluation and multidisciplinary process used to evaluate the social, economic, organisational and ethical issues of a health intervention or health technology.

Figure 1: Ireland's Medtech Sector

For further information on Ireland's Medtech Sector please see appendix 1.

2. Innovation & Healthcare

Innovation is about finding new ways to create solutions using new technologies, new applications of existing technologies, and new models for services and solutions - in order to improve patient outcomes, enhance efficiency, improve processes or extend the reach of care (4). Innovative medical technology solutions can improve clinical and non-clinical outcomes and have the potential to reduce overall treatment costs.

Innovation is not just about new devices; it's about value creation. An idea that is not transformed into social or economic value is not considered innovation. Within the healthcare system, innovation can improve the quality and efficiency of health services, thus contributing to improved population health. For example, through invention of new products / services, innovation can decrease waiting times, length of hospital stays, morbidity and mortality. In addition to obvious social and patient care benefits, innovation can also contribute to the affordability of healthcare services, a major challenge in healthcare systems (4).

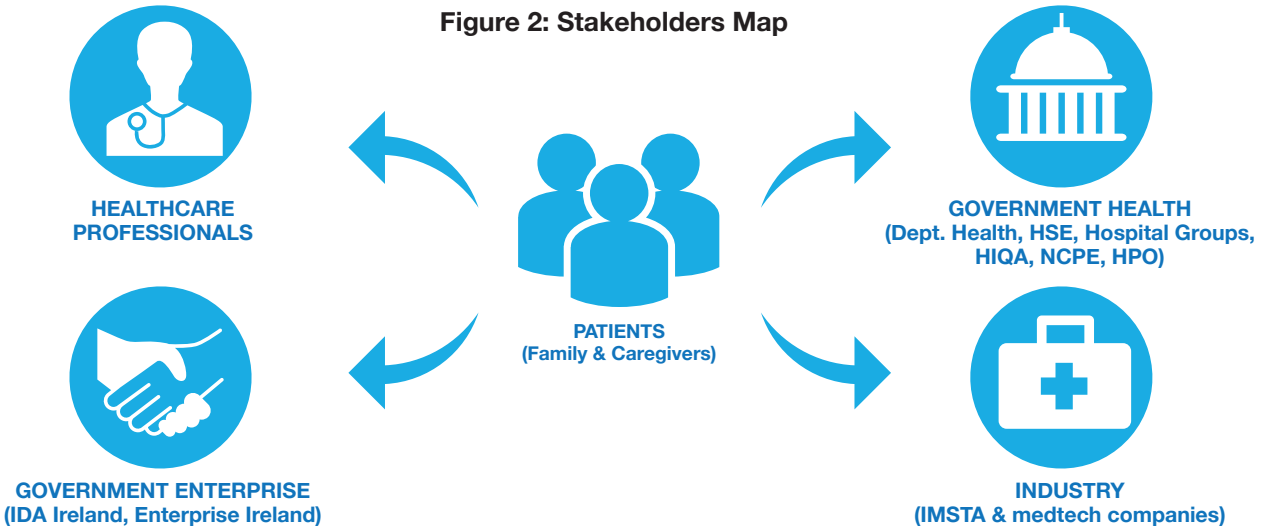
An informed focus on innovative, procured with a full awareness of societal benefits and healthcare outcomes, is a critical factor in sourcing successful healthcare solutions. Greater societal expectations about better healthcare outcomes and accountability of results have been a major driver of global policy reforms in the delivery of healthcare. Our ageing population will require a greater range of ever improving healthcare services. It is therefore important, more than ever before, for healthcare providers to really understand how medical technologies can improve patient outcomes and create value. Value-based health care enables the true value of medical technologies to be measured by understanding and taking into account the needs of patients, healthcare professionals, providers and the health system. It includes innovation, sustainability and socio-economic impact.

When it comes to health care service delivery, patients, payers, and governments are asking for improved results: better access, faster diagnosis and treatment, more convenience, greater sensitivity to patient needs and so on. The challenges Ireland faces today call for a more innovative approach to evaluating the medical technologies that will provide the most clinically and cost effective health care solutions within an internationally accepted decision making evaluation process.

Recommendation:

Include value-based health care methodology into medical technology assessment and procurement.

Figure 2: Stakeholders Map



3. Healthcare in Ireland

With an ageing population and an increasing incidence and prevalence of chronic illness, Ireland's health care system is under pressure. The most recent CSO health survey found that 32% of Ireland's adult population reported that they have a long-standing illness or health problem, and half of those aged 55 and over reported health problems (5).

The same survey also found that 22% of Ireland's population smokes, 81% of the population drinks alcohol and 53% of the population are overweight or obese. Over one in ten have been admitted to a hospital as an inpatient in the last 12 months and one in four have been absent from work due to a health related problem (5).

Ireland's public health spend of almost 20% of total government expenditure was the highest in the European Union in 2014 (6,7). Despite the high health spending, the OECD data in its 'Health at a Glance 2015' report show that Ireland had the worst incidence of asthma and COPD (chronic obstructive pulmonary disease) of 32 countries surveyed, and ranks 24th for rates of stroke deaths (8). Ireland also rates poorly for number of hospital beds; adult obesity; alcohol consumption and female life expectancy at age 65 (8).

In 2015 the HSE spent over €13 billion on pay and non-pay items, approx. €500m of which was spent on medical technologies, which equates to 3.8% of total expenditure which is less than both the EU average (6.3%) and UK spend (4.7%) (3).

Healthcare is in a time of transition. Growing patient cohorts are putting a strain on budgets and at the same time patients rightfully expect immediate access to high quality healthcare and beneficial treatments. Healthcare systems will have to respond to this mounting pressure.

Key questions are a). How to eliminate inefficiencies in current healthcare delivery? b). How to drive outcomes that matter to patients and carers and c). How to obtain best value for money? (9). Ireland's healthcare challenges need to be driven by innovative approaches and closer engagement of stakeholders.

Recommendation:

The health system must be able to clearly identify the most clinically useful and cost-effective medical technologies if it is to manage the burgeoning health care challenge.

Figure 3: The Irish Health Survey 2015, CSO statistical publication, 16 November 2016

4. Ireland's New Activity Based Funding System[4]

The Irish hospital system delivers 1.6 million procedures per annum, most of which are coded from patient charts to HIPE[5] by clinical coders in hospitals (10). Under the recently introduced Activity Based Funding (ABF) system, a clear picture of hospitals' costs is now required as all future payments made to hospitals will be based on coded data. The introduction of the ABF system is a major change in the way hospitals in Ireland will be funded and should put the allocation of funds on a more transparent and equitable footing.

Hospitals will now be paid for the actual quantity and quality of care they deliver to patients, thereby enabling the hospitals to clearly see the link between money and the work they carry out. Hospitals can now assess their cost competitiveness, identify key cost drivers and enable change that will drive value (10).

As the ABF system matures, it will be able to set National tariffs of fixed prices that reflect national average costs. Each tariff price will be made up of many constituent parts which can be unbundled. The key purpose of unbundling is to put incentives in place that encourage appropriate alternatives to traditional hospital 'bundles of care'. In theory this should encourage service innovation and improvements in quality, by rewarding providers whose services attract patients and by focusing negotiations between providers and commissioners on quality and innovation.

However, it is important to ensure that where medical technologies are used that they are appropriately costed for the new ABF system, so that patients will have fair access to innovative procedures and treatments, and Ireland can build a sustainable health care service into the future. If medical technologies are not valued appropriately, price can become the main driver for adoption, which may lead to inferior healthcare and suboptimal outcomes for patients and the healthcare system.

A recent OECD Economic Survey recommended that Ireland improve efficiencies in health spending by fully implementing "money follows the patient" and publishing improved indicators of financial and operational performances of hospitals (8) while the Minister for Health Simon Harris T.D., addressing the Oireachtas Committee, also emphasised the importance of ramping up Activity Based Funding (11).

Improved efficiencies in health spending will be difficult to achieve without visibility of reference costs and tariff prices, which will in turn impede the development of value based healthcare proposals, as budget impact cannot be explored in the development of such proposals. Publication of Ireland tariff and reference costs pricing is best practice.

Recommendation:

Ensure medical technologies are appropriately costed in the new ABF system.

4 Formerly known as "Money follows the Patient"

5 The Hospital In-Patient Enquiry Scheme (HIPE) is a database system that collects information on hospital day cases and in-patients in Ireland.

5. Evaluating Medical Technologies

An important precursor to the costing of medical technologies within a procedure is the acknowledgement that the procedure itself, including the medical technology, is of value to the health care system. Procurement authorities globally are increasingly using Health Technology Assessments when evaluating and sourcing medical technologies (12).

Health Technology Assessments

A Health Technology Assessment (HTA) is a systematic evaluation and multidisciplinary process used to evaluate the social, economic, organisational and ethical issues of a health intervention or health technology. The purpose of an HTA is to provide independent evidence to justify the purchase of best-in-class medical technologies when finite budgets need to be balanced. HTA information should always be generated with reference to unbiased experts involved in clinical practice (12).

Table 1: **Benefits of Health Technology Assessments (HTAs)**[6]

1	Provides appropriate health care decision making platform
2	Proven effectiveness, safe & cost effective
3	Exposes the decision making process to scrutiny
4	May be required for reimbursement
5	Ensures rational use of resources
6	Establish systematic & predicable process for introduction of new innovative treatments
7	Can assist in removing obsolete technologies
8	Provides Patients with quick access to new treatments
9	Increases coordination, cooperation & transparency
10	Provides for suitable KPIs as a method to assess performance objectively

6 Adapted from NYE Metoder (2016)

6. International Experience

The process of undertaking medical technology HTAs varies between and within countries. There are numerous HTA units and initiatives across member states in Europe (13). Currently however, the majority of these units are assessment units for pharmaceuticals. The role HTAs play in pharmaceuticals is very different from that played in medical technologies. Typically, assessments on innovative drugs inform decision makers about pricing and reimbursement, the same is not true for medical technologies where a necessary strategic link between assessment and decision can be missing in many EU countries (9). Focusing on pharmaceuticals alone distorts medical decision making with regard to resource investments and patient care.

Table 2: **Medical Technologies' Distinctive Features**[7]

1	Medical Technologies have a greater product diversity and shorter product life cycles which encourages rapid innovation
2	Devices can have multiple applications
3	Devices can be diagnostic where both the value of the improved diagnostic capability & the value of improvement in patient outcome needs to be measured
4	It can be difficult to gather comparative clinical & cost effectiveness data for Medical Technologies
5	Devices frequently undergo product modifications over time
6	The skill set & experience of caregivers using the device is important as is the associated learning curve
7	Organisational adjustments can be associated with introduction of a new device e.g training, work practices etc.
8	It may be difficult to undertake Random Controlled Trials due to no formal legislative requirement, fewer patient numbers and shorter follow up periods
9	Dynamic Pricing – Medical devices typically show rapid decreases in price due to incremental innovation & market entry of competitors' products claiming equivalence without the same evidence base, which clearly impacts the calculation of the incremental cost-effectiveness ratio (ICER).
10	Medical devices are linked with a process, a process that can often be as important as the device

7 Adapted from Drummond et al. (2009) "Economic Evaluation for Devices and Drugs - Same or Different?" ISPOR Value in Health 12(4) 402-404

Most distinctive features of medical technologies cannot be fully assessed at market entry. However, their potential impact could be modelled, based on the experience with previous medical technologies, in order to make a preliminary recommendation. Then, well-designed post-market studies could help in reducing uncertainties and make policymakers more confident to achieve conclusive recommendations (14). The assessment of medical technologies needs to be managed by decision-makers when coverage and reimbursement policies are being considered.

MedTech Europe estimates that HTAs are only performed in a limited number of countries in Europe, and this only covers 1% (by volume) of new technologies each year (9). Jurisdictions and health authorities vary in their prescribed methods for conducting HTAs and information on individual processes can be difficult to find. In general terms, an HTA is about combining evidence of clinical effectiveness and economic benefits.

Some established medical technologies HTA programmes include:

- ***The Medical Technology Evaluation Programme & Technology Appraisal Guidance, NICE, England & Wales***
- ***The National System for Managed Introduction of New Health Technologies, Norway***
- ***GBA, IQWIG and DIMDI, Germany***
- ***Scottish Health Technologies Group/Health Improvement, Scotland***

Each of these four systems, outlined in brief below and described in the appendices, evaluates medical technologies to determine whether the case for adoption and / or reimbursement is supported by evidence. Each believes that the systematic evaluation of new technologies provides evidence-based access for patients to new improved treatments.

The Medical Technology Evaluation Programme & Technology Appraisal Guidance, NICE, England & Wales

The well recognised National Institute for Health & Care Excellence (NICE) elects and evaluates medical technologies to determine whether the case for adoption in the NHS in England and Wales is supported by the evidence through Medical Technologies Evaluation Programme (MTEP) (15). New medical technologies that have the potential to offer substantial benefits to patients and the NHS are likely to be adopted more consistently and more rapidly if NICE develops guidance on them (15,16). On 1 April 2017 NICE introduced a fast track appraisal (FTA) process, which aims to speed up access to the most cost-effective new treatments (17).

For further information please see appendix 2.

The National System for Managed Introduction of New Health Technologies, Institute of Public Health, Norway

The Norwegian Institute of Public Health is responsible for the Medical Technologies Health Technology Assessments (18). The Norwegian Healthcare system implemented the HTA system to provide an appropriate systematic decision-making tool that serves as a predictable process for the introduction of new medicines and technologies. They believe that the evaluation of new technologies has allowed for improved patient safety, provides patients with quick access to new treatment and a framework to assist in the divesting of obsolete treatments. It has assisted their healthcare system to be more cost effective and assist the rational use of resources. It has also helped increase coordination, cooperation & transparency amongst stakeholders (18).

For further information please see appendix 3.

German Federal Joint Committee (GBA), the Institute for Quality and Efficiency in Health Care (IQWIG) and the DIMDI.

In Germany, health-care decision-making occurs at Parliament level where the Ministry of Health is responsible for setting the framework for health care in Germany. However, the bodies involved in HTA in Germany are the German Federal Government (GBA), the Institute for Quality and Efficiency in Health Care (iQWiG) and the DIMDI (19, 21 and 22). The G-BA is the highest decision-making body in health care composing of doctors, dentists, hospitals, patients and statutory health insurance funds. G-BA is responsible for the assessment of new diagnostics and medical devices and follows a standardised procedure founded on the principles of evidence-based medicine; the effectiveness, quality and economic viability of treatments are assessed (20, 21). The iQWIG carries out assessments on effectiveness, quality, and efficiency of new technologies and provides recommendations on behalf G-BA or the Ministry of Health but does not determine the G-BA's final decision (20). DIMDI develops and operates database-supported information systems, and produces HTA reports that aim to inform health policy (20).

For further information please see appendix 4.

The Scottish Health Technologies Group, Health Improvement Scotland

The Scottish Health Technologies Group (SHTG) provides advice on the clinical effectiveness and cost effectiveness of existing and new healthcare technologies that are likely to have significant implications for patient care in Scotland. The SHTG advisory group was set up to provide assistance to NHS Scotland boards when considering selected health technologies (23).

Healthcare Improvement Scotland, on behalf of the SHTG, publishes a range of evidence review reports. These include evidence notes (rapid reviews), systematic reviews and health technology assessments. SHTG produces an Advice Statement to accompany each of these evidence review reports (24). The SHTG Advice Statements outlines the clinical effectiveness, safety and cost effectiveness evidence for the technology in question in the context of NHS Scotland (25). The advice statements assist NHS planners and decision makers in NHS Scotland. The SHTG aims to present a balanced and impartial critical appraisal and summary of the research evidence about new technologies, and / or new evidence about existing technologies. The SHTG sets out to act as an 'honest broker' when interpreting the evidence and to provide independent and unbiased advice (25).

For further information please see appendix 5 – 9.

7. Situation in Ireland

The Health Information and Quality Authority (HIQA) has responsibility for the Health Technology Assessment of Health Technologies in Ireland and has assessed a number of medical technologies as part of larger National programmes e.g. HTA of Mechanical Thrombectomy for Stroke (26).

Similarly, the National Centre for Phamacoeconomics (NCPE) focuses on the HTA of pharmaceutical products to ascertain if a new drug should be placed on the state's reimbursement list and comments on the proposed cost. The NCPE has in the past also reviewed a small number of medical technologies as part of pharma studies.

However, today in Ireland the vast majority of medical technologies do not undergo a formal HTA evaluation and are placed on the market without a structured assessment of their value and costs. The lack of a HTA framework can also mean that new and innovative medical technologies do not become established in the market and are not adopted by healthcare givers, including doctors, nurses and allied professionals and consequently the potential benefits to patients and society are lost.

While the Department of Business, Enterprise & Innovation agencies are working to support the medical technologies sector to grow and develop in Ireland through manufacturing, competitiveness and research initiatives, the Department of Health agencies are limited in their capacity to encourage the adoption of innovative medical technologies, due to a lack of a systematic evaluation framework and perceptions on budgetary limitations. As a result, products and services run the risk of being assessed on cost alone and international research findings conclude that a singular focus on procurement price / price reduction can result in a failure to reduce total healthcare costs (27). It is estimated that 70% of global medtech sales go through a public-procurement process and that 70% of those are determined on the basis of price alone, which leads to less competition in the market place, reduces innovation, discourages adoption of new technologies and does not consider the patient, patient outcomes, or other health care costs within the system (28).

Consistent with industry concerns that medical technologies were not being systematically evaluated using an HTA framework, the HSE are currently setting up a new internal medical technology assessment unit that will be based in Limerick and managed by a Public Health Medicine consultant. The proposed HTA unit will be modelled on the Scottish Health Technologies Groups (SHTG) HTA system. The process is expected to include a screening step to help identify new technologies, mini-HTA assessments to include a clinical specialist, preparation of evaluation reports, and advice notes for HSE/ HBS Procurement summarizing findings but not instructing purchasing decisions.

A systematic and transparent selection process of the medtech products to be assessed should be included, whatever the final assessment methodology.

Recommendation:

Develop an appropriate, fit for purpose, evaluation process and methodology for medical technologies in Ireland based on internationally accepted Health Technology Assessment principles.

8. Conclusion

Ireland's health service and patients need access to the most clinically and cost effective treatments. Medical technologies have an important role to play in enabling innovative healthcare solutions. Having an appropriate HTA Framework for medical technologies will provide patients, clinicians and the healthcare system with the ability to evaluate these solutions and reward those technologies that provide positive outcomes for stakeholders.

Measuring value outcomes can be achieved in many ways and while Ireland can certainly take lessons learnt from existing International Health Technology Frameworks, research suggests that one should also be cautious in implementing another country's system in full since all HTA entities are creations of existing individual healthcare systems in which they are based and may not transfer seamlessly from one healthcare system to the next.

Without a systematic HTA framework, the true value of medical technologies will not be realised and the ABF system presently being introduced will not be able to readily identify medical technologies that create value and help build efficiencies for hospitals and better outcomes for patients.

As mentioned previously, it is not necessary to subject all medical devices or technologies to a rigorous HTA. Only step change, innovative or high cost technologies with very significant national budgetary impact would need to undergo a HTA-type evaluation process. Less complex technologies could be assessed using simpler evaluation methodologies, such as mini-HTAs, which can by their nature be undertaken regionally or locally.

For many indigenous medtech companies, a systematic HTA framework would provide the evidence necessary to allow Irish innovations access overseas markets, as the clinical efficacy and cost-effectiveness of the health products would have been independently assessed in the market of origin.

While the proposed HSE Health Technology Assessment unit is a welcome development, its introduction should be considered in the context of its' inter-relationship to the existing HTA agencies HIQA and NCPE, the Health Research Board, the Health Products Regulatory Authority and the Department of Business, Enterprise and Innovation agencies.

Recommendation:

A forum should be established to advise the Department of Health on the setting up of a standardised framework for evaluating medical technologies for use in the health service.

9. Key Recommendations

- **Include value-based health care methodology into medical technology assessment and procurement.**
- **Identify the most clinically useful and cost-effective medical technologies for the health system to manage the burgeoning health care challenge.**
- **Ensure medical technologies are appropriately costed in the new ABF system.**
- **Develop an appropriate evaluation process and methodology for medical technologies in Ireland based on internationally accepted Health Technology Assessment principals.**
- **Establish a forum to advise the Department of Health on the setting up of a standardised framework for evaluating medical technologies for use in the health service.**

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Appendices

Appendix One:

Medical Technologies Sector in Ireland

The growth of the medical technologies sector is closely tied to increasing global health care spend mainly attributable to ageing populations and the prevalence of chronic diseases. However, the pressure to reduce costs, increase efficiencies, and provide value to stakeholders remains intense for medical technology suppliers everywhere.

Ireland is Europe's largest Medical Technology cluster and is globally recognized as a Centre of Excellence for manufacturing and a growing reputation in research and development. There are over 300 companies employing 29,000 people (29) with thirteen of the world's top 15 companies having operations here. Indeed Ireland has the highest number of personnel per capita employed in Medtech in Europe (1).

As a leading cluster for medical device products globally, exports of medical devices and diagnostic products now represent 8% of Ireland's total merchandise exports (1). As the second largest exporter of Medtech products in Europe, Ireland supplies 95 of the world's top 100 countries (ranked by GDP). Over 25% of the world's population suffering from diabetes, rely on injection devices made in Ireland. An impressive 50% of ventilators in acute hospitals worldwide and 33% of the global supply of contact lenses are manufactured in Ireland (1).

Ireland has also been ranked number one globally for the exchange of technology and ideas and boasts 5 clinical research facilities, which support patient-focused research (1). The business environment and government assistance is responsible for an impressive 60% of medtech companies in Ireland engaging in research and development activities (1). The industry is closely integrated with key academic research centres of excellence, including AMBER (TCD), Tyndall National Institute, BDI (DCU), SEAM (WIT) and APT (AIT) (1). Ireland's medical technologies sector is well positioned to drive R&D activities and provide innovative solutions to both patients and healthcare systems.

Continued Government support and investment to formalize and consolidate a systematic Health Technology Assessment Framework would further serve to re-affirm its intention to support Ireland's position as a global leading medtech cluster. This investment will enable the adoption of cutting edge medical technologies and innovative solutions, many of which will have been researched and ultimately manufactured in Ireland.

New medtech innovations are being developed across the globe faster than ever before including the world's smallest pacemaker (30), the first bio absorbable stent (31) and needle-free diabetes care (32). Innovative products and services often demand higher upfront cost due to large R&D investments incurred. However, measuring beneficial value outcomes over the lifetime of the patient could deem innovations more affordable for health systems in the longer term. As companies develop better healthcare solutions with greater benefits to the patient, healthcare providers and the wider community, Ireland needs to find a better way to systematically evaluate these medical technologies.

Appendix Two:

The Medical Technology Evaluation Programme (MTEP) & Technology Appraisal Gudiance, NICE, England & Wales

The MTEP process has been designed so that guidance is developed for the NHS in an open, credible, transparent and timely way, allowing appropriate input from relevant stakeholders. The process takes approximately 48 weeks, which includes a 10 –12 week period where a technology submission is checked for eligibility and another 38 weeks to complete the evaluation process (15,16).

NICE typically evaluate Medical Technologies by cost consequence or interventional procedure guidance (safety and efficacy). NICEs methodological approach to HTAs has been deemed as fairly rigorous. Company reports and Independent Technology Assessment Reports are expected to conform to a clear set of methodology guidelines. NICE are seen as transparent in the evaluation process and procedures as they publish all evidence except for some commercially sensitive data e.g. unpublished clinical trials. Stakeholder involvement is encouraged from the early scoping exercise, manufacturers also have the opportunity to submit data and analyses, and there is also an opportunity to comment on group reports and the opportunity to appeal (15,16).

Although NICE is an “arms length” organisation there have been accusations that NICE is following the Government or Payers agenda and some concerns over the length of time to conduct an assessment which can take over 50 weeks (33).
NICE use the following appraisal to assess technologies: the Single Technology Appraisal, the Multiple Technology Appraisal and the Fast Track Appraisal. The Single Technology Appraisal (STA) assesses a single drug or treatment. The STA process is typically used for new technologies - usually new pharmaceutical products or license extensions for existing products. A Multiple Technology appraisal (MTA) assesses several drugs or treatments used for 1 condition. A MTA is used if a new topic for an appraisal is particularly complex and not suited for the single technology appraisal process. On 1 April 2017 NICE introduced a fast-track appraisal for technologies that offer exceptional value for money. The aim is to provide quicker access for patients to the most cost-effective new treatments.

If a positive recommendation is made through the FTA process, NHS England/commissioners have committed to providing funding for the technologies within 30 days of guidance publication.

Appendix Three:

The National System for Managed Introduction of New Health Technologies, Institute of Public Health, Norway

The Norwegian Ministry of Health & Care Services is made up of 4 Regional Health Authorities and agencies including the Directorate of Health, Radiation Protection Authority, Medicines Agency and the Institute of Public Health. Norway has a population of 5 million (18). It is the Norwegian Institute of Public Health that is responsible for the Medical Technologies Assessments. There are three types of HTAs carried out: Mini HTA (a limited assessment at hospital level), Single Technology Assessment (STA) (an assessment at National level focused on single health technology) or a Full HTA (a broad assessment carried out at National level) (18).

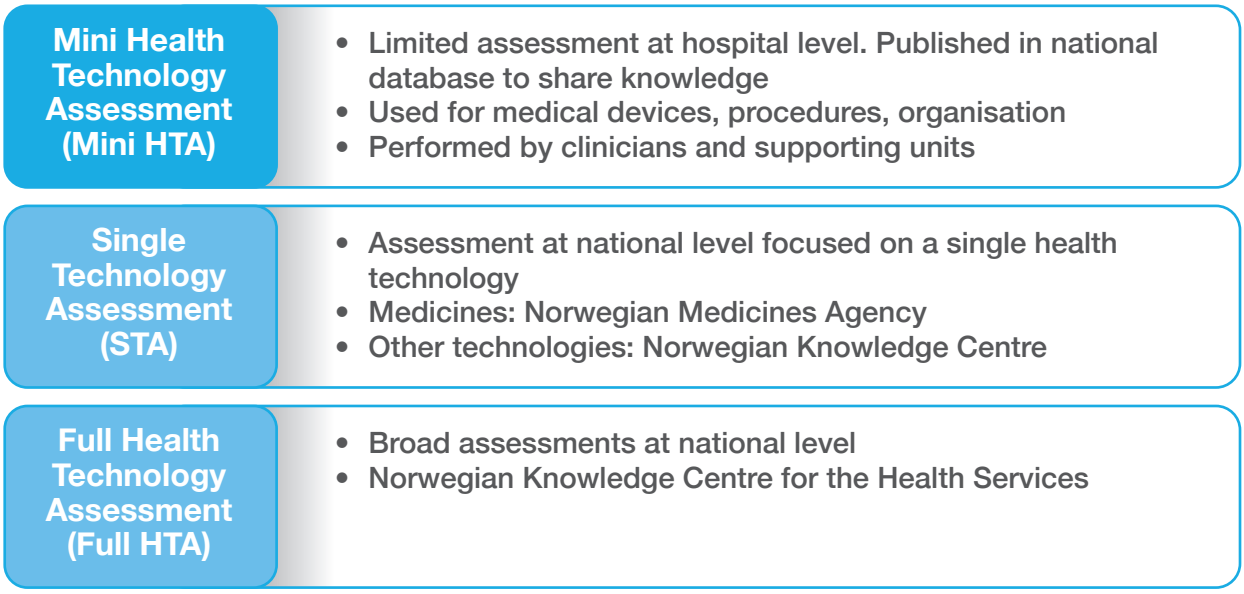

Figure 4: Three categories of HTAs in Norway

The Norwegian Healthcare system implemented the HTA system to provide an appropriate systematic decision-making tool that serves as a predictable process for the introduction of new medicines and technologies. The evaluation of new technologies has allowed for improved patient safety, provides patients with quick access to new treatment and a framework to assist in the divesting of obsolete treatments. It assists the healthcare system to be more cost effective and assist the rational use of resources. It also helps increase coordination, cooperation & transparency amongst stakeholders (18).

Process map

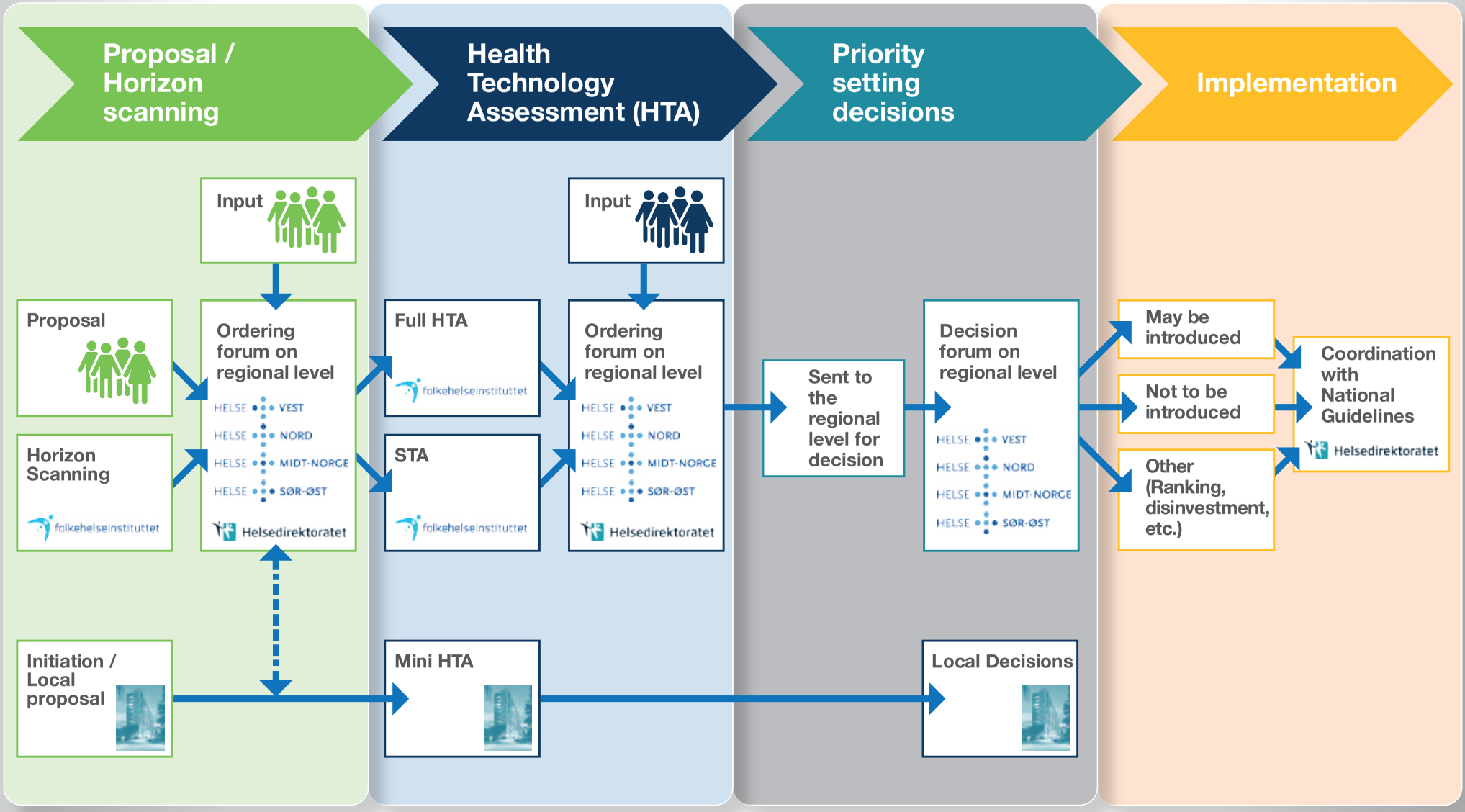

Figure 5: NYE Medical Technologies HTA Process Map[6] (Norway)

6 This process map was amended for medtech HTA with the kind assistance of the NYE Metoder Sekretariat

Appendix Four:

German Federal Joint Committee, The Institute for Quality and Efficiency in Health Care and DIMDI, Germany

The bodies involved in HTA in Germany are the German Federal Government (GBA), the Institute for Quality and Efficiency in Health Care (iQWiG) and the DIMDI (20). G-BA is the highest decision-making body in health care composing of doctors, dentists, hospitals, patients and statutory health insurance funds. G-BA is responsible for the assessment of new diagnostics and medical devices (20). The G-BA assessment of medical treatments follows a standardised procedure founded on the principles of evidence-based medicine; the effectiveness, quality and economic viability of treatments are assessed (20, 21).

In 2004 G-BA set up The Institute for Quality and Efficiency in Health Care (iQWiG) as an independent scientific unit. The G-BA or the Ministry of Health can now commission IQWiG to carry out technology assessment of diagnostic, therapeutic methods and pharmaceuticals. IQWiG can also award scientific commissions to external experts to fulfill its commitments toward the G-BA.

IQWIG assessments on effectiveness, quality, and efficiency of new technologies provides recommendations on behalf G-BA or the Ministry of Health but does not determine the G-BA's final decision (20). IQIWG does not conduct clinical studies but searches the scientific literature to identify relevant studies. New technologies must increase life expectancy, reduce the duration of disease reduce symptoms and complications, or improve quality of life (21).

The non-drug interventions department in IQWIG assesses the advantages and disadvantages of non-drug interventions. They include treatments such as surgical procedures, radiation therapy and dental procedures (21). IQWig publish all scientific reports and detailed information on its website (21).

Finally the German Institute for Medical Documentation and Information (DIMDI) develops and operates database-supported information systems, and produces HTA reports that aim to inform health policy (22). HTAs driven by DIMDI rarely play a role in funding and reimbursement of treatments nevertheless they could play an important role for health policy decisions by Government (20,22).

Appendix Five:

Scottish Health Technologies Group, Health Improvement Scotland, Scotland

Health Improvement Scotland's (HIS) purpose is to drive improvements that support the highest possible quality of care for the people of Scotland. The Scottish Health Technologies Group (SHTG) is part of a wider organisation that provides advice on the clinical and cost effectiveness of healthcare technologies that are likely to have significant implications for patient care in Scotland.

The SHTG is an advisory group set up to provide assistance to NHS Scotland boards when considering selected health technologies. The remit of the SHTG is to provide advice on the evidence surrounding the clinical and cost effectiveness of existing and new technologies likely to have significant implications for patient care in Scotland (24).

Healthcare Improvement Scotland, on behalf of the SHTG, publishes a range of evidence review reports. These include evidence notes (rapid review taking 1-6 months to produce), systematic reviews and health technology assessments (HTAs). The evidence review reports (with the exception of HTAs) do not make recommendations for NHS Scotland. SHTG has a role to produce and publish an Advice Statement to accompany each of these evidence reviews (24).

SHTG Advice Statements outline the view of the SHTG on the clinical effectiveness, safety and cost effectiveness evidence for the technology in question in the context of NHS Scotland (24). The advice statements are intended to assist NHS planners and decision makers as one source of information needed for decision making and planning in NHS Scotland. SHTG advice does not override the individual responsibility of health professionals to make decisions in the exercise of the clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer (24).
HTAs will also consider patient issues, organisational issues and ethical considerations (24).

The SHTG aims to present a balanced and impartial critical appraisal and summary of the research evidence about new technologies, and / or new evidence about existing technologies. The SHTG sets out to act as an 'honest broker' when interpreting the evidence and provide independent and unbiased advice (24).

The SHTG has around 25 members and meets five times a year. The group has a range of interests, experience and expertise. Some members represent professional networks and all NHS boards are invited to participate. Members include representatives of National Procurement, NHS board chief executives, directors of finance and planning, industry representatives and clinical groups such as directors of medicine and public health are also represented. There are currently four public partners who are full members of the SHTG.

Stakeholders are invited to suggest topics of interest to the Scottish Health Technologies Group. Anyone can complete a topic referral form including the NHS boards, clinicians, manufacturers and members of the public.

The SHTG's Innovative Medical Technology Overview (IMTO) process allows manufacturers or sponsors of a new health technology to submit evidence about clinical and cost effectiveness for review. An IMTO aims to contribute to local NHS decision-making and may improve the chances of the adoption of a new and effective technology across the NHS.

The Evidence Review Committee (ERC) is a subgroup of the SHTG, which selects new topics to be taken forward. It also prepares draft advice based upon reviews of evidence for the SHTG and helps to guide the evidence review process and meets monthly.

Figure 6: Scottish Health Technologies Group Advice

Scottish Health Technologies Group Process

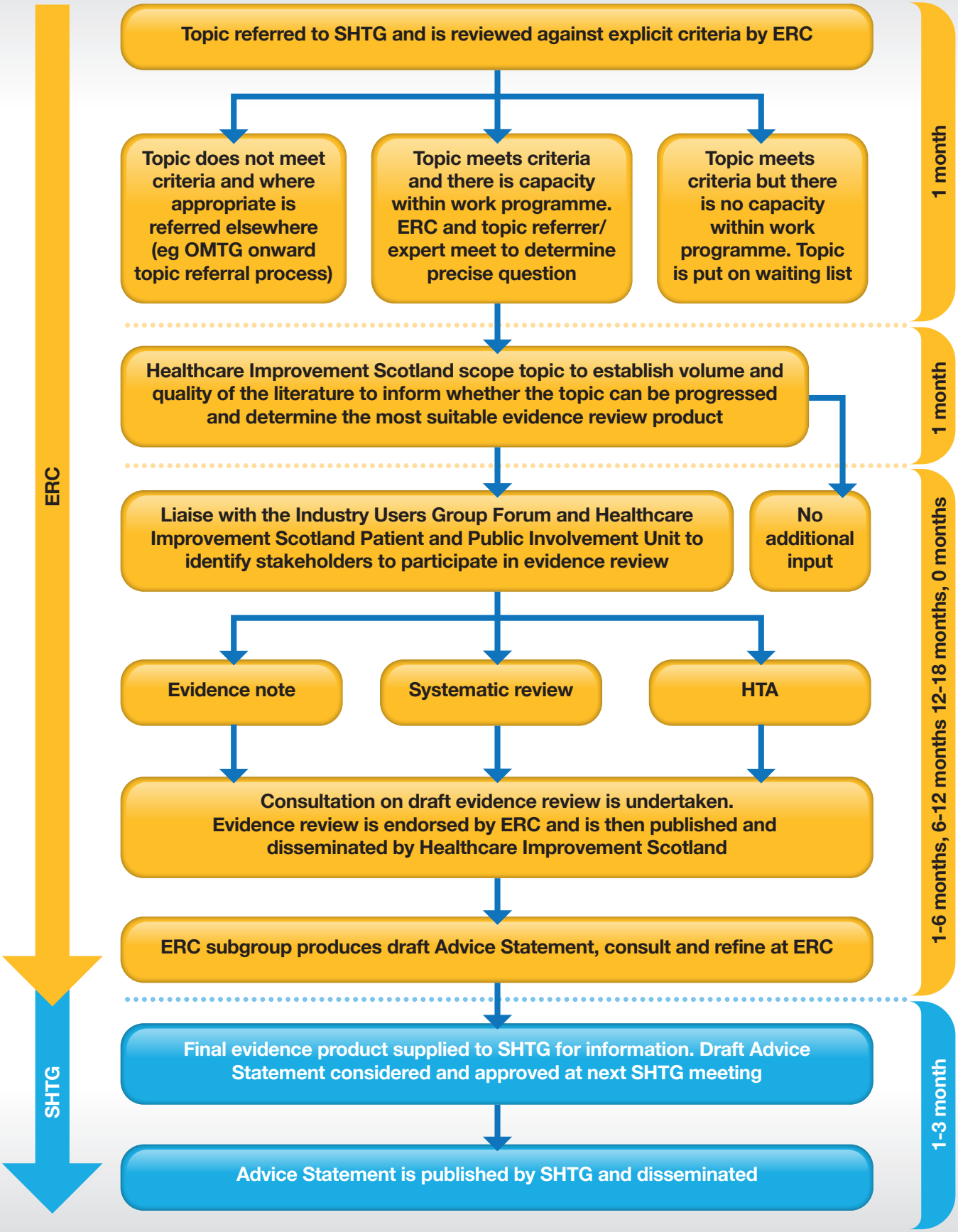

Figure 7: Scottish Health Technologies Group Process

Appendix Six:

Pharmac, New Zealand

Pharmac is the Government agency that decides which pharmaceuticals to publicly fund in New Zealand. Pharmac was established in 1993 to ensure that New Zealanders get the best possible health outcomes from money the Government spends on medicines used in the community. Their role has expanded to include cancer medicines, vaccines, and haemophilia treatments, which are all funded by District Health Boards through the Combined Pharmaceutical Budget (CPB). PHARMAC also makes decisions about the medicines funded in DHB hospitals and negotiates national contracts for medical devices used in hospitals.

Pharmac are working towards budget management of hospital medicines and medical devices in the longer term. Since its establishment, PHARMAC has increased the range of subsidised medicines available and met the cost of growth in demand for existing medicines within the amount of funding provided each year.

In 2013 Pharmac started to work with medical technologies as they planned to take over medtech evaluation from 2015. The expectation is that the PHARMAC model will achieve value for money and allow people around the country to have equitable access to treatments wherever they live. PHARMAC's work in hospital medical devices demonstrates seeking suppliers in a category that may not provide significant immediate savings, but provides the critical base upon which future, more substantial savings are driven. PHARMAC is prepared to forego the temptation to chase short-term benefits if doing so will enable it to realize the longer-term benefits.

Under a mature management approach PHARMAC will use its capabilities to select new technologies that offer the best health outcomes, whilst restricting uptake of others. Utilize its strong buyer-power to negotiate the terms of supply for new technologies, even where competition is limited. Ensure suppliers of substitutable products compete with each other on quality, price and supply terms in an effort to reach market-efficient terms. Ensure value is capable of being retained or deployed by the funder, rather than diverted in the supply chain.

Pharmac are currently reviewing wound care, sutures, disposable laparoscopicdevices, interventional cardiology, orthopaedic products, sterilisation packaging products and associate consumables, medical thermometer products, single-use instruments, surgical gloves, hand hygiene and venous thromboembolism prevention devices (34).

Appendix Seven:

The National Health Care Institute/ Zorginstituut Netherlands (ZIN), Netherlands

The National Health Care Institute's aim is to maintain the quality, accessibility and affordability of health care in the Netherlands under 5 key areas:

- **Managing the basic health care package**
- **Encouraging improvements in health care quality**
- **Advising on innovations in health care professions and education**
- **Implementing arrangements for special groups of (un)insured persons**
- **Funding (35).**

Appendix Eight:

EUnetHTA

EunetHTA was established to create an effective and sustainable network for appointed Government HTA agencies across Europe, it includes 79 HTA organisations from all 28 EC member states, Norway and Switzerland. In October 2016, Ireland's HIQA's Director of HTA was elected Chair of the EUnetHTA Assembly (26). Due to Brexit the UK HTA organisation NICE will no longer play a role in the EUnetHTA. The EUnetHTA is working to harmonise HTA methodologies across the EU by 2020 ensuring better standards (36).

Appendix Nine:

INAHTA

The International Network of Agencies for Health Technology Assessment connects HTA agencies to each other for knowledge sharing and as a forum for the promotion of other interests of HTA agencies. The membership typically meets face to face once a year (37).

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