Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Technology Assessment of Scheduled Procedures

Analysis of Ethical Issues

December 2013

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive continuous improvement in Ireland's health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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1 Introduction

For healthcare systems, difficulties arise when there are requirements to simultaneously increase access, decrease costs, and improve the quality of the care provided. As healthcare resources are finite, this can make it challenging, if not impossible, to provide everyone with every effective intervention they might need or want. A balance between the expectations of different patients and a fair distribution of publicly-funded resources is required to allow for the best outcomes for the most people.

The Health Information and Quality Authority's (the Authority or HIQA) *National Standards for Safer Better Healthcare* describe a vision for high quality, safe healthcare and the standards required to achieve this. These include that 'service users have equitable access to healthcare services based on their assessed need' and based on the 'best available evidence, and in line with relevant eligibility criteria'.[1] Clinical referral or treatment thresholds can help to ensure that patients' access to healthcare services is based on their assessed clinical needs irrespective of their geographical location. Thresholds should be in line with best available evidence to achieve the greatest outcomes for patients by ensuring that the right patient receives the required treatment at the right time.

There is no obvious set of ethical principles or analytical tools to determine how to allocate finite resources and to ensure equitable access to a system that delivers maximal healthcare benefit for those available resources.[2] However, allocation should take into account a range of ethical considerations including fairness, respect for autonomy, responding to individual need and benefitting the wider population. One of the most widely used frameworks in decision making in healthcare is from Beauchamp and Childress, which outlines four principles: beneficence, non-maleficence, autonomy and justice (see Table 1 on the following page).[3] Daniels and Sabin have proposed another four principles for consideration when prioritising healthcare called 'accountability for reasonableness'.[4] The principles are: transparency, relevancy, an appeals process and a mechanism for challenge and dispute (Table 1).

Table 1. Principles in ethical analysis.[2]

Principle	Description
Beauchamp and Childress' four principles:[3]	
Autonomy	*Respecting decision-making capacities of autonomous persons; enabling individuals to make reasoned informed choices.*
Beneficence	*Doing or bringing about good.*
Non-maleficence	*The avoidance of doing harm.*
Justice	*Distributing healthcare fairly and justly.*
Daniels and Sabin's four principles for 'accountability for reasonableness':[4]	
Transparency	*Public visibility of ethical framework/principles/rationale behind priorities.*
Relevancy	*Priorities based on evidence, reasons and principles agreed by, e.g. patients, clinicians.*
Appeal	*Opportunity to review decisions in light of new evidence/circumstances.*
Mechanism for challenge / dispute	*Appropriate governance and accountability structures to ensure above conditions met.*

The core health technology assessment (HTA) model developed by the European Network of HTA agencies (EUnetHTA[†]) applies some of these principles in determining the ethical issues associated with a medical or surgical intervention (Appendix 1).[5] These principles, and the EUnetHTA core model, are considered in this section with respect to the ethical impact of threshold introduction in the Irish healthcare system.

In the current healthcare system, it is unclear if the distribution of elective healthcare is equitable, if those who need treatment are getting it, and those who need it most are getting it first. The introduction of clinical referral or treatment thresholds should ensure more transparent and equitable access. The principles of autonomy, beneficence and non-maleficence, justice and those underpinning 'accountability for reasonableness' are discussed in detail in the following sections. Ethical issues specifically associated with a particular procedure are documented in the discussion section of the chapter dedicated to that procedure. For example, the difficulties of applying thresholds for grommet insertion are discussed with respect to limited access to audiology.[6;7] Similarly, the difficulty of applying a criterion that

[†] European Network of 63 health technology assessment (HTA) agencies, the collaboration consists of government-appointed organisations, regional agencies and not-for-profit organisations that produce, or contribute to HTA.

specifies maximum conservative care should be exhausted prior to a patient being referred for specialist review for a range of musculoskeletal conditions is discussed in the context of existing difficulties in accessing physiotherapy and occupational therapy in the primary care setting.[8] The need for a holistic view is outlined with regard to the importance of measuring the effect of a cataract on a patient's lifestyle and not on visual acuity alone in the HTA on cataract surgery.[9] Finally, a timely, safe, effective, equitable and patient-centred referral system depends on the quality of the information provided in the referral letter. This is discussed further in a national HIQA report and is beyond the scope of these HTAs.[10]

2 Ethical principles

2.1 Autonomy

Beauchamp and Childress define autonomy as 'Respecting decision-making capacities of autonomous persons; enabling individuals to make reasoned informed choices.' In the context of the allocation of finite resources, respect for individual autonomy to choose certain treatments may conflict with other values such as equity or the need to benefit the wider community. The introduction of clinical referral or treatment thresholds can sometimes be thought of as rationing of healthcare by restricting patient choice. Restricting choice could be considered an infringement on a patient's right to personal autonomy. However, this right, particularly in the healthcare setting, is not absolute. Difficulty may arise, for example, in the management of patient expectations of what should reasonably be available. The medicalisation of health[‡] may have an impact on some patients' views on their need for surgery, particularly for procedures or interventions perceived as cosmetic or aesthetic[§] in nature (this does not include reconstructive[**] surgery). While offering potential improvements in self-esteem, these procedures may have little impact on morbidity and mortality. This medicalisation can increase pressure on waiting lists as problems are being defined as health conditions that previously would not have resulted in demands for healthcare.[12]

Clinical referral or treatment thresholds should consider any important impact on the patient's quality of life in addition to their views on receiving treatment.[13] Some

[‡] The identification or categorisation of a condition as being a disorder requiring medical treatment or intervention
[§] Aesthetic or cosmetic plastic surgery aims to correct an inharmonious but normal shape of the body, without any clinical necessity being present and is performed at the patient's request.[11]
[**] Reconstructive plastic surgery is related to the restoration of appearance and function following congenital deformity, accidents, burns or cancer.[11]

procedures may have limited potential to improve the patient's length of life; however, they may have potential to make improvements in the patient's quality of life. The extent of this improvement depends on how concerned the patient is by the symptoms, how much the symptoms impact on their ability to function and to what extent symptoms are improved by treatment. It is essential, therefore, that the physician determines what outcomes are important to the individual patient. However, it should be noted that thresholds that rely on value judgments may be difficult to apply uniformly, potentially resulting in unequal access to treatment.

Operating on a patient who would not want the operation if they were fully informed of the risks, benefits and alternatives is ethically questionable. It should be noted that for patients with reduced decision-making capacity (e.g. young children) their family or primary care giver should participate in the decision-making process. Physicians should ensure that patients are fully informed of the reasons for non-referral, risks versus the benefits of having a procedure, the skill and experience of the physician providing the procedure and the likely impact on the outcome, and any potential outcomes of not having or delaying the intervention. An opportunity should be offered to review the decision and/or seek another opinion if required.[14] The UK King's Fund (2012) reports that well informed patients consume less medicine.[15] An international Cochrane Review that included 11 trials involving major elective surgeries showed that demand declined by 20% after patients became well informed. There was consistent evidence noted that as patients became better informed, they made different decisions and felt more confident.[16]

2.2 Beneficence and non-maleficence

Under Beauchamp and Childress' principles, beneficence relates to 'doing or bringing about good' and non-maleficence to 'the avoidance of doing harm'. In the context of clinical referral or treatment thresholds, ethical issues may arise for patients who have limited clinical capacity to derive benefit from a procedure. Every procedure carries an inherent risk; procedures should not be performed unless the benefits outweigh the risks or there is a clear positive impact on the length or quality of life for the patient. For cosmetic procedures, the potential for clinical benefit is limited in terms of changes in morbidity or mortality. While the procedure may improve the patient's self-esteem, it may conflict with the payer's requirement to maximise overall population health gain. For non-cosmetic procedures, there is a need to balance the risk of the intervention against the capacity to benefit; this decision should take account of other available treatment options. The potential for harm or benefit for those other than the patient may also impact the decision – for example,

the potential for reduced parental absenteeism following tonsillectomy for recurrent tonsillitis in a child. Careful consideration of these issues is required.

Patients have a right to refuse unwanted treatment, but do not have a right to access treatment that a physician believes may cause more harm than good, or where they deem that the patient is not suitable to access the treatment as they are considered unlikely to cooperate or make the lifestyle changes required to make the treatment effective.[14] Again, if treatment or referral is refused, this must be explained to the patient with the reasons and an opportunity should be offered to review the decision and/or seek another opinion.[14] Difficulties may arise when a patient, rather than presenting as an exceptional case, is on the cusp of a threshold. In these and all situations, the physician should exercise their clinical judgment and do what is in the best interest of the individual patient while remaining mindful of their responsibility in ensuring equitable access to finite healthcare resources.[14] This is in line with Medical Council's Guidelines that state that the physician has 'a duty to assist in the efficient and effective use of healthcare resources and to give advice on their appropriate allocation. While balancing a duty of care to the individual patient, they should be aware of the wider need to use limited healthcare resources efficiently and responsibly. Such awareness should inform decision making in their clinical practice.'[14]

2.3 Justice

'Distributing healthcare fairly and justly.' One of the main challenges in introducing clinical referral or treatment thresholds is to ensure that individuals have fair and equitable access to treatments based on their assessed clinical needs. The development of thresholds should avoid creating further inequity by creating criteria that could inappropriately exclude certain individuals.

As noted above, the introduction of clinical referral or treatment thresholds can sometimes be thought of as rationing of healthcare. Some form of rationing is an inevitable part of any healthcare system and rationing decisions are made at varying levels 24-hours-a-day.[17] For example, physicians make micro-rationing decisions about a patient's capacity to benefit, the number of tests they should undergo etc.. Managers and politicians make macro-rationing decisions to ensure resources are not wasted and to balance competing needs given the resources available. The various approaches to rationing in healthcare systems include: waiting lists (a form of rationing by delay); limiting the introduction of new technologies (a form of rationing by denial); strict budget limits (requiring physicians to engage in bedside rationing); and the application of thresholds (a form of rationing by selection).[17]

Rationing by selection is not a new phenomenon: a survey of purchasing plans from health authorities in England published in 1995 showed that 40 out of 129 authorities at that time were restricting funding for certain treatments, particularly those considered to be more cosmetic, for example, surgical treatment of asymptomatic varicose veins.[18] It has been suggested that the question is not whether rationing itself is unethical, but whether the distribution mechanisms are structured and organised in ways that will promote fair and equitable access to healthcare.[19] Furthermore, it has been recommended that the structure and organisation of healthcare cannot be left to chance or interest, but must be planned and implemented in ways that make explicit the principle of justice.[19]

2.4 Transparency, relevancy, appeal and a mechanism for challenge / dispute

Transparency, relevancy, appeal and a mechanism for challenge or dispute with respect to decision making in healthcare are defined in Table 1 above. These HTAs aim to identify clinical referral or treatment thresholds for interventions for which clinical benefit may be limited unless undertaken within specific limits, so that resources may be diverted to those who will benefit most. Therefore, the approach to clinical referral or treatment threshold generation should be evidence based, transparent, relevant, and include all key stakeholders (patients, healthcare practitioners and healthcare managers) in the process. If clinical referral or treatment thresholds are implemented, it is imperative that there are opportunities for appeal and mechanisms to ensure good governance.[4] Such an appeals process should be fair and meet strict criteria to protect against overuse of the 'exceptional cases' criterion. Identification of the body with responsibility and accountability for the governance of clinical referral or treatment thresholds is important to ensure that consistency and appropriateness applies to all national thresholds and to ensure that the thresholds are updated as appropriate to reflect developments in medical research, so that they continue to reflect best practice. Good governance ensures that any changes to clinical referral or treatment thresholds are evidence based, transparent and open to public and expert debate and discussion. However, it should be noted that threshold implementation, the development and implementation of an appeals process and exceptional cases criteria is beyond the scope of these HTAs.

3 Current practice

With respect to scheduled procedures, self-referral to specialists is not the standard of care in Ireland. Within the publicly-funded healthcare system, medical doctor to medical doctor referral is the norm, that is, patients are typically accepted for

specialist review based on a referral by their primary care physician or by a secondary or tertiary care specialist. Once a referral has been made, the subsequent decision about whether to treat the patient is made by the hospital specialist. A King's Fund report in 2010 noted that, in the UK, not all referrals are necessary in clinical terms; a substantial proportion of activity is discretionary and avoidable, with some primary care practitioners referring patients based on their 'desire for referral'.[20] Some described this as an 'occasional' influence, whereas others reported that it was a major driver of their referrals.[20] It was also noted that there is evidence of late referral in certain specialties, suggesting that some patients in need of referral are not referred until their condition has reached an advanced stage.[20]

Currently in Ireland a form of rationing by delay takes place in the public healthcare system as demand for care cannot be satisfied with the available resources. This is evident from the long waiting lists for outpatient appointments to see a hospital consultant and subsequently for elective procedures following a decision to treat.[21;22] Waiting lists can influence demand in various ways: some may not receive the treatment they need in time, thus experiencing unacceptable adverse consequences, while others with conditions that may be self-limiting (e.g. recurrent tonsillitis, ganglia) may experience resolution of their symptoms, removing the need for intervention. Long waiting lists may prompt some primary care practitioners to refer patients simultaneously to several lists in order to expedite access to care, or to refer patients early to account for anticipated natural progression of the patient's condition during the expected waiting times, assuming that the deterioration will be sufficient that intervention will be warranted by the time the patient is reviewed. However, this ultimately makes the waiting lists less efficient. The Council of Europe's report on managing waiting lists states that patients should not be added to a waiting list to reserve a place against the possibility that in the future treatment might be warranted.[12] The implementation of referral criteria should help to improve the consistency of referral and shorten waiting lists by ensuring that patients who do not meet the referral criteria are not waiting unnecessarily on lists.

Variations in treatment may also exist. A UK King's Fund report (2011) on variations in healthcare noted that there is a professional consensus that when an intervention is effective, there tends to be little or no variation in clinical practice (e.g. surgery following a hip fracture).[23] However, clinical practice variations exist (e.g. for tonsillectomy) where there is weaker evidence and professional uncertainty that hospital admission is effective.[23] Variation in clinical practice is reported internationally.[13] Wennberg's International Collaborative report (2011) states that most of the variation in care is unwarranted and cannot be explained by differences

in health or differences in patient preferences.[13] A recent study reported that caesarean delivery rates ranged from 7% to 70% in US hospitals. In lower-risk pregnancies, where more limited variation might be expected, rates varied fifteen-fold (2% to 37%). They reported that these vast differences in practice patterns are likely to drive the costly overuse of caesarean delivery.[24] The use of standardised treatment thresholds may help reduce unnecessary variation and allow for the more efficient use of resources without causing harm or reducing benefit.

The European directive on cross-border healthcare[25] was approved in 2011 with a deadline for transposition into Irish law of October 2013. The directive provides clarity about the rights of patients who seek reimbursed healthcare in another member state.[25] Reimbursement is restricted to treatments typically provided within the member state up to the cost of the treatment in the home state. Prior authorisation may be required if the healthcare involves an overnight stay in a hospital or if it requires use of highly specialised or cost-intensive medical infrastructures or equipment. As such, a clear definition of the therapeutic procedures ordinarily available to patients within the publicly-funded healthcare system in Ireland and in what context is imperative to ensure transparency and equity of access. To ensure patient safety, the directive states that 'the Member State of affiliation may refuse to grant prior authorisation if the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare'.[25] Since cross-border healthcare requires retrospective reimbursement of treatment by the state and does not include payment for travel and accommodation, this may mean that those who cannot afford to pay upfront or to absorb the cost of travel and accommodation will be restricted from accessing care through this route.

As noted, current healthcare budgets in Ireland are partly contained by rationing healthcare by delay (i.e., waiting lists that limit the total number of patients treated) due to finite budgets and limited capacity within the system. The cross-border healthcare directive will reduce constraints due to limited capacity as patients will be free to obtain healthcare in other EU countries where there is excess capacity available. However, the cost of this healthcare will still need to be absorbed within the existing budget; this will potentially reduce the ability of the system to prioritise the provision of healthcare to those with the greatest clinical need or the greatest capacity to benefit through patient triage (rationing through selection). As noted in Section 2.3, rationing of healthcare itself may not be unethical, rather the question is if the distribution mechanisms are structured and organised in ways that will promote fair and equitable access to healthcare. The introduction of stated clinical

referral and treatment thresholds could help provide clarity around the use of certain procedures whose benefits may be limited except when undertaken within strict clinical criteria, so that the maximum population benefit can be gained from the available healthcare budget.

The use of referral or treatment thresholds similar to those recommended in these HTAs may already be in use by some primary care practitioners and hospital consultants. However, there may be differences in the extent or type of thresholds used or in the documentation of same. In the absence of evidence-based, stated referral criteria, variation in referral patterns is likely to continue. Evidence-based thresholds could potentially increase or decrease the demand for certain services in some regions – for example, if the threshold is set below that which is widely used at present, or if it generates increased referrals to services providing alternative treatments. This should be considered during threshold generation. Use of standardised referral criteria should help reduce outpatient waiting lists by identifying those patients that would be better managed at a primary care level. This should streamline the patient's elective journey, reducing waiting times for patients most in need of treatment. Introduction of formal referral criteria may not reduce the overall number of surgeries that are performed annually as many hospitals are already operating to capacity and have extensive waiting lists. As noted however, with the implementation of the cross-border healthcare directive in October 2013, patients will have the right to be reimbursed for healthcare that they obtain in other EU countries if they are ordinarily entitled to this healthcare in Ireland. This could significantly increase healthcare expenditure in certain areas as capacity constraints will be reduced; however, there could be continued issues in terms of the equitable provision of care due to variation in the clinical need of those obtaining care given that there may be disparities in the types of patients willing or able to travel to access treatments for which they have been referred.

An ethical framework for healthcare priority setting and resource allocation has been used in other countries. The National Health Service (NHS) Commissioning Board in the UK published a framework in April 2013 that outlined the 15 core principles that should guide decision-making by commissioners to ensure they fulfil their dual mandate of meeting all reasonable requirements for healthcare, while remaining within their allocated resources. These core principles include the need for decisions to be: consistent and equitable, providing equal access for individuals with equal clinical need; and to be founded on evidence of cost-effectiveness, so that care is affordable and demonstrates value for money based on the needs of the population served.[(26)]

4 Other outcomes of implementing clinical referral or treatment thresholds

Use of threshold criteria that restrict access to certain procedures in the public healthcare system may divert patients to the private healthcare system. This treatment may be undertaken at the patient's own expense if they do not have private health insurance or if their insurance policy does not cover the treatment. Healthcare systems and insurers typically define the packages of care that they provide and operate particular discretion in terms of procedures viewed as more cosmetic in nature that do not reduce morbidity or mortality. There is ample evidence of healthcare procedures that are not covered by either public or private insurers except under very limited criteria.[27-32] This in itself does not represent inequity if there is transparency in relation to the thresholds and they are applied in an equitable fashion; and if there is no evidence that the alternatives offered in the private system are more effective than those offered in the public system.

5 Conclusions

Clinical referral or treatment thresholds should balance patient expectations with their assessed clinical need allowing for a fair distribution of resources and the best outcomes for the most people. The ethical principles of autonomy, beneficence, non-maleficence, justice and accountability and reasonableness were considered with respect to the impact of threshold introduction on the delivery of health services. Ethical issues of relevance to threshold introduction include the need for informed consent, the need to balance the needs and expectations of the individual patient against those of the wider population, and the capacity of the patient to benefit from the procedure. The principle of justice requires that resources are distributed fairly and equitably.

Clinical referral or treatment thresholds can be thought of as rationing of healthcare; rationing by itself is not unethical and is an inevitable part of any healthcare system. Rather, the question is if the distribution mechanisms are organised to promote fair and equitable access. There is currently rationing of healthcare in Ireland through waiting lists. The transposition into Irish law of the directive on cross-border healthcare may significantly change this situation as certain patients may expedite their access to care by travelling to another EU country with available capacity. The healthcare budget is finite, however, so other mechanisms to ensure fair and equitable access to healthcare will be necessary. The use of evidence-based, transparent thresholds that are based on clinical need and have been developed in

consultation with all stakeholders should help reduce variation in referral and treatment patterns and ensure more equitable and timely access to necessary care based on clinical need. If clinical referral or treatment thresholds are implemented, it is imperative that access issues to the specialist services incorporated into the thresholds are improved and that there are opportunities for appeal mechanisms to ensure good governance.

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Appendix 1 – EUnetHTA core model for medical and surgical interventions: ethical analysis

Topic	Issue	Clarification	Response
Principal questions about the ethical aspects of technology	Is the technology a new, innovative mode of care, an 'add on' to a standard mode of care or a replacement of a standard?	The consequences of totally new models of care are likely to be more difficult to predict than the consequences of replacing an old technology (for individual values, attitudes and expectations as well as for healthcare systems). Novel, innovative treatment modes may require extra emphasis on ethical analysis, although the literature and research base for the topic may be narrow.	Not assessing a new technology, assessing the application of thresholds to procedures currently used.
Principal questions about the ethical aspects of technology	Can the technology challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements?	It is important to identify those groups within the society for whom the use of the technology may pose serious challenges due to their beliefs, convictions or current social arrangements (e.g. need of blood transfusion adjunct to the use of the technology, contraception). Identification of these conflicts and finding other, acceptable possibilities to treat the condition in these groups is important. Identifying the conceptions behind the beliefs and values may help put them in perspective, when considering the overall acceptability of the technology. Technology may also change generally accepted social arrangements by challenging traditional conceptions (e.g. assisted reproductive technologies have separated the concept of genetic, biological and social motherhood).	Assigning thresholds to the procedures assessed to date are not predicted to challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements.

Principal questions about the ethical aspects of technology	What can be the hidden or unintended consequences of the technology and its applications for different stakeholders?	In addition to intended use, the technology may be used for other purposes and have side-effects in addition to those following from the intended use. Unintended consequences are obviously difficult to predict, but the intended purpose and uses of the technology should be evaluated against the likely uses and consequences of the technology in the real world. New technologies tend to lead to new areas of inventions and give rise to new ethical questions (e.g. in vitro fertilisation (IVF) and development of genetic testing has led to questions of pre-implantation genetic diagnostics (PGD). As pre-symptomatic and prenatal genetic tests have become available, the healthcare system has to be prepared to handle moral issues raised by true positive and false negative findings.) Many treatments have indirect effects also on relatives.	The application of thresholds may have indirect effects on families. For example, if a tonsillectomy is delayed then family members may have to take time off work to look after a sick child.

Autonomy	Does the implementation or use of the technology challenge patient autonomy?	Patients have in most cases a right to autonomy, i.e. the right to be self-governing agents. This requires the right to decide about things of importance to oneself on one hand, but also relevant information and a capability to understand the information, consider it in relation to personal values and decide accordingly. Thus, technologies and health systems may interfere with the patient's right to autonomy directly or indirectly by influencing the decisional capacity. For example, a technology that does not allow itself to be understandably explained to the patient (e.g. gene therapy for dementia) is potentially problematic, as are treatments that require patients to behave in a certain way (e.g. liver transplants given conditional to not drinking).	Patient autonomy is discussed in **Section 1.1** of this report.

Autonomy	Does the implementation challenge or change professional values, ethics or traditional roles?	Technologies may change the relationship between physician and patient, challenge professional autonomy or otherwise interfere with professional ethics and values. The patient-physician relationship is traditionally based on mutual trust, confidentiality and professional autonomy so that individual treatment decisions can be made in the best interest of the patient. Technologies that interfere with core virtues and principles of medical and professional ethics challenge the professional integrity of the physicians or other healthcare professionals. Technologies that align with professional ethics are more likely to be implemented successfully.	Patient autonomy is discussed in **Section 1.1** of this report. Introduction of evidence-based clinical referral / treatment thresholds for procedures where effectiveness may be limited for some patients unless undertaken within strict clinical criteria should not interfere with professional ethics or the physician-patient relationship.
Human dignity	Does the implementation or use of the technology affect human dignity?	Technologies that are applied especially for persons with reduced autonomy (children, mentally impaired, severely ill) may violate a person's dignity, i.e. challenge the idea that all human beings have intrinsic moral value, and should thus not be seen as means to others' ends.	For some of these procedures the patients may have reduced autonomy, e.g. children, old patients; in these situations their families would participate in the informing process. See **Section 1.1**.

Human integrity	Does the implementation or use of the technology affect human integrity?	Technology can challenge human integrity by preventing (or even tempting) people (patients or professionals) to live according to their moral convictions, preferences or commitments. This is especially important for vulnerable patient groups. Integrity can also be seen as a coherent image or identity of oneself. Thus, for example, prenatal diagnostics might challenge the integrity of people who value new life as gift; cochlear implants are problematic for those who do not see deafness as a disability. Institutions that discourage honesty or ethical conduct more generally are detrimental to integrity (for example, systems where lying about one's health state might lead to better treatment than being honest).	Thresholds that rely on value judgments may be difficult to apply uniformly, potentially resulting in unequal access to treatment. See **Section 1.1.**

Beneficence/ non-maleficence	What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not implementing the technology? Who will balance the risks and benefits in practice and how?	The decision to implement new technology requires careful decision on the balance between benefit and harm, cost-effectiveness, reallocation of resources etc.. When this decision has been made, the decision on individual patient level rests on both the professional who offers the technology and the patient who autonomously accepts the use of technology in her/his situation. The individual decision has to be based on objective information on possible benefits and risks. Risks are only justified to the extent they are needed to create benefits. If not proven otherwise, the individual patient is generally to be seen as the best judge of risks and benefits for her/himself.	Beneficence/non-maleficence is discussed in **Section 1.2** of this report.

Beneficence/ non-maleficence	Can the technology harm any other stakeholders? What are the potential benefits and harms for other stakeholders, what is the balance between them? Who will balance the risks and benefits in practice and how?	Some technologies have the potential to unfold unwanted or harmful effects, not only on the patients that the technology is directly applied to, but also indirectly on other stakeholders (relatives, other patients, organisations, commercial entities, society etc..) Benefits and harms to individuals must be balanced with benefits and harms that can befall society as a whole (social utility, maximising public health). These harmful effects may manifest in the physical, social, financial or even other domains of life. For example, results of genetic tests may negatively interfere with family planning and social life of not only the individual being tested but also of his or her relatives.	Beneficence/non-maleficence is discussed in **Section 1.2** of this report.

Justice and equity	What are the consequences of implementing / not implementing the technology on justice in the healthcare system? Are principles of fairness, justness and solidarity respected?	A new intervention may require reallocation of human resources, funding and training. A large reallocation of resources may seriously jeopardize other patient groups (e.g. new technology that requires human resources in acute care). How this reallocation affects the existing healthcare system has to be studied for all stakeholders? Can the technology be applied in a way that there is equal access to those in equal need? How can this be guaranteed? Could potential discrimination or other inequalities (geographic, gender, ethnic, religious, employment, insurance) prevent access? Are specific safeguards needed? How will possible caregivers' burden and wellbeing be influenced? Potential inequalities and discrimination should be justified.	Justice is discussed in **Section 1.3** of this report. Current threshold introduction aims to provide equal access to those in equal need without discrimination.
Justice and equity	How are technologies presenting with relevant similar (ethical) problems treated in the healthcare system?	Clearly presenting how relevantly similar technologies are treated in a healthcare system may help to adopt coherent and just health policies, either by applying past precedents to current cases, or showing that past cases need reconsideration. Similarity is to be defined individually for each technology. The idea is to concentrate only on the similarities relevant for solving the ethical problems found important for the current HTA project. The similarity may be, for example, of medical, technological, economical, ethical, social, organisational or legal nature.	The international literature was reviewed to assess how threshold introduction was applied. Similar thresholds to those recommended in these reports have been applied internationally.

Rights	Does the implementation or use of the technology affect the realisation of basic human rights?	Human rights exist both in ethics and legislation, most notably in the United Nations declarations and related statements, like the Council of Europe's biomedicine convention. Basic human rights are universal and consider the most important goods, protections and freedoms. Classes of rights are civil and political rights, social rights, minority and group rights and environmental rights. For HTA, perhaps the most relevant are the rights to equality, non-discrimination, safety, adequate standard of living and healthcare. For example: right to life, liberty and security of person; right to a standard of living adequate for the health and wellbeing of him/herself and of his/her family, including medical care and necessary social services, and the right to security in the event of sickness, disability or old age; right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health.	Introduction of evidence-based clinical referral / treatment thresholds for procedures where effectiveness may be limited for some patients unless undertaken within strict clinical criteria should not interfere with the patient's rights.

Legislation	Is legislation and regulation to use the technology fair and adequate?	Technology may lead to ethical problems that make current regulation inadequate (e.g. ethical reflection is needed when considering what kind of regulation is needed). This consideration is done on the basis and in combination with the legal domain. Emphasis should be put on considering the ethically relevant aspects and consequences of current law, needs for legal regulation that have arisen from the ethical analysis, and a global assessment of the adequacy of the legislation based on all available information.	Not assessing a new technology, assessing the application of thresholds to procedures currently used.

Appendix 2 – Treatment Abroad Scheme (TAS) requirements

Treatment Abroad Scheme requirements[33]

The Health Service Executive (HSE) operates a Treatment Abroad Scheme (TAS) for people entitled to treatment in another EU/EEA member state. The TAS provides the cost of approved treatments in another EU/EEA member state or Switzerland. The TAS allows a medical or surgical consultant based in Ireland to refer a patient that is normally resident in Ireland for treatment in another EU member state or Switzerland, where the treatment in question meets the following criteria:

(a) The application to refer a patient abroad has been assessed and a determination given before that patient goes abroad.

(b) Following clinical assessment, the referring consultant certifies the following:

- They recommend the patient be treated in another EU/EEA country or Switzerland.
- The treatment is medically necessary and will meet the patient's needs.
- The treatment is a proven form of medical treatment and is not experimental or test treatment.
- The treatment is in a recognised hospital or other institution and is under the control of a registered medical practitioner.
- The hospital outside the state will accept EU/EEA form E112 (IE).

A person ordinarily resident in the Republic of Ireland may be referred abroad by an Irish based consultant for treatment that is:

- Among the benefits provided for by Irish legislation.
- Not available in Ireland.
- Not available within the time normally necessary for obtaining it in Ireland, taking account of his/her current state of health and the probable course of the disease.

Published by the Health Information and Quality Authority.

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