Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

A series of health technology assessments (HTAs) of clinical referral or treatment thresholds for scheduled surgical procedures

Background and Methods

April 2013

Safer Better Care

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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Acknowledgements

The Authority would like to thank all of the individuals and organisations who provided their time, advice and information in support of these health technology assessments (HTAs).

Particular thanks are due to the Expert Advisory Group (EAG) and the individuals within the organisations listed below who provided advice.

The membership of the EAG is as follows*

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Dr Anne Flood, Director of Midwifery and Nursing, Letterkenny General Hospital, nominated by the Director of Nursing and Midwifery Services, HSE‡

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Dr Alan Smith, Director of Performance Improvement (Scheduled Care), Special Delivery Unit and Acting CEO, National Treatment Purchase Fund

* This assessment is conducted on a phased basis. The first phase consists of analysis of clinical referral or treatment thresholds for otolaryngology, ophthalmology and vascular scheduled surgical procedures. Members representing these clinical specialities are included on the next page.

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[‡] Note: Marie Tighe is currently deputising for Dr Anne Flood (Director of Midwifery and Nursing).

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^Note: Mr Paul Moriarty, Consultant Ophthalmologist, Royal Victoria Eye and Ear Hospital, Dublin, deputised for Mr Paul Connell at the first EAG meeting.

Organisations that assisted the Authority in providing information, in writing or through meetings, included:

Economic and Social Research Institute (ESRI)

Health Service Executive (HSE)

National Treatment Purchase Fund (NTPF)

Members of the Evaluation Team

The members of the Authority's Evaluation Team are: Dr Patricia Harrington, Patrick Moran, Dr Linda Murphy, Michelle O'Neill, and Dr Máirín Ryan.

Conflicts of Interest

None reported.

[‡] Marie Tighe is currently deputising for Dr Anne Flood (Director of Nursing and Midwifery).

List of abbreviations that appear in this report

ADVS	Activities of daily vision scale
ALOS	Average length of stay
BIA	Budget impact analysis
BMI	Body mass index
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness analysis curve
CEAP	Clinical etiology anatomy pathophysiology
CI	Confidence interval
CVZ	College voor zorgverzekeringen (NL)
dB	Decibels
dBHL	Decibels hearing loss
dBA	A-weighted decibels
DNA	Did not attend
DRG	Diagnosis related group
EAG	Expert advisory group
ENT	Ear, nose and throat
ESRI	Economic and Social Research Institute
GP	General practitioner
HIPE	Hospital In-Patient Enquiry
HRQoL	Health-related quality of life
HSE	Health Service Executive
HTA	Health technology assessment
ICD-10AM/ACHI	International Classification of Diseases – 10th revision Australian Modification / Australian classification of health interventions
ICER	Incremental cost-effectiveness ratio
IPG	Interventional procedure guidance (NICE)
NHS	National Health Service (UK)

NICE	National Institute for Health and Care Excellence (UK)
NTPF	National Treatment Purchase Fund
OME	Otitis media with effusion
OPD	Outpatient department
OSA	Obstructive sleep apnoea
PCRS	Primary Care Reimbursement Service
PCT	Primary Care Trust (NHS, UK)
PTR	Patient Treatment Register (collated by the NTPF)
QALY	Quality-adjusted life year
RCSI	Royal College of Surgeons in Ireland
RCT	Randomised controlled trial
SD	Standard deviation
SDB	Sleep disorder breathing
SIGN	Scottish Intercollegiate Guidelines Network

1. Introduction to Technical Report

1.1 Background to request

On 4 October 2012, the Director General designate of the Health Service Executive (HSE) requested that the Health Information and Quality Authority (the Authority) undertake a series of health technology assessments (HTAs) of scheduled surgical procedures. This was in the context of evaluating the potential impact of introducing clinical referral or treatment thresholds for such procedures within the publicly funded healthcare system. The purpose of this assessment is to provide advice on possible thresholds for a number of relevant high volume procedures.

Need and demand for healthcare services is increasing, with demand for elective procedures continuing to exceed available capacity. These increases are driven in part by our aging population; the 2011 Census reported a 14.4% increase in the population aged 65 years or over compared to 2006, with a 100% increase noted for those aged 100 years and older.[(1)] Need is also driven by development of new or improved interventions that are effective in treating healthcare problems. Although potentially providing improvements in the safety, efficacy or range of care options available, invariably this is at an increased cost. Finally, growth in demand may also be fuelled by changes in lifestyle, in particular the increase in overweight and obesity that contribute to disease and lead to increased demand for services such as bariatric surgery to assist weight loss.

As a result of increased demand, pressure on national waiting lists continues to grow despite increases in overall activity levels. Demand for scheduled surgery in particular continues to exceed available capacity, with the HSE reporting a 22% increase in demand for these procedures in 2011 compared to 2010. Targets have been set and are routinely monitored by the HSE for hospital elective medical and surgical procedure waiting times for both adults (100% waiting times within 0-6 months of referral) and children (100% waiting times within 0-3 months of referral).

Significant progress with inpatient elective surgery waiting lists has been made, with National Treatment Purchase Fund (NTPF) data indicating that while over 49,000 patients were on waiting lists for elective medical or surgical procedures in September 2012, 86% were on the waiting list for less than six months.[(2)] The HSE's Outpatient Data Quality Programme to collate and monitor national outpatient waiting times commenced in 2011. This data is not complete as not all hospitals are currently reporting. However, the data is now of sufficient volume and quality that public reporting has started. Data from the HSE Performance Report for October 2012, indicated that there were over 388,000 patients waiting for a first outpatient

appointment, 48% of whom were waiting over six months and 29% over 12 months.[3]

A 2011 report, published by the King's Fund in the UK which examined differences in admission rates for a range of routine surgical procedures, concluded that there is evidence of persistent, unwanted variation in healthcare. The report highlighted research that there is little or no variation in clinical practice when there is strong evidence and a professional consensus that an intervention is effective. In contrast, clinical practice variations are found to exist where the evidence is weaker and there is professional uncertainty that a procedure is effective. It concluded that unwanted variation in healthcare can directly impact equity of access to those services, population health outcomes and the efficient use of resources.[4] In Ireland, data from the Hospital In-Patient Enquiry (HIPE) system suggest that there is evidence of variation in surgical rates for scheduled procedures across regions. This variation may reflect inequitable access to necessary surgery or differences in treatment thresholds applied by specialists.

The HSE has set itself a challenge of achieving greater efficiencies within its finite budget. National Clinical Programmes have been established for each discipline to improve and standardise patient care throughout the organisation, with a goal of improving the quality for all users, to improve access to services, and to improve the cost-effectiveness of the services provided. The Elective Surgery Programme has been established with an aim of improving the elective surgical journey of the patient by providing better access and processes, defined care pathways and monitored clinical outcomes. These improvements will be delivered through four components: the Average Length of Stay Programme that aims to reduce the average length of hospital stay; the Audit Programme that monitors national outcomes; the Productive Theatre Programme that uses process improvement to improve theatre utilisation; and the Guidelines Programme that aims to standardise best practice. It notes that a goal of any quality improvement programme is to 'perform the right procedure for the right patient at the right time in the right way'. The application of appropriate criteria for surgery is included as having a role in further improvement to the patient's elective surgical journey.[5]

The aim of this HTA is to provide advice on potential clinical referral or treatment thresholds for procedures where effectiveness may be limited for some patients unless undertaken within strict clinical criteria. By restricting such procedures in patients who may derive limited clinical benefit, there may be potential to free capacity for treatments of higher clinical value thus maximising population health gain for the finite resources available.

Interventions offered should offer a significantly greater potential for benefit than harm at an affordable cost; those patients who are most likely to benefit from certain interventions and least likely to be harmed should be clearly defined. Increased clarity around referral or treatment thresholds for general practitioners (GPs) and patients should minimise, where possible, referral to surgical outpatients of patients who do not proceed to surgery. The benefits include appropriate management of patient expectations, reduced inappropriate referral to surgical outpatients, shortening of the patient's elective surgical journey and standardisation to best practice.

Streamlining referrals to tertiary care should help ensure that the right patients are referred for treatment at the right time, potentially releasing capacity and resources without causing harm or reducing benefit. The use of transparent criteria may allow for more efficient audit to ensure that there is equity of access to beneficial care throughout the system.

1.2 Terms of Reference

Based on the available evidence, the Health Service Executive (HSE) will consider if specific clinical referral or treatment thresholds should apply to certain scheduled surgical procedures currently provided by the publicly funded healthcare system. In consultation with the Special Delivery Unit of the Department of Health, key questions in relation to the type of procedures to which thresholds may apply, the appropriate thresholds for these procedures and the potential impact of the thresholds were developed. Answers to these questions, which underpin the Terms of Reference of this HTA, will inform the decision of the HSE.

The Terms of Reference are:

- Identify and assess high volume scheduled surgical procedures currently undertaken in Ireland to which it would be appropriate to examine clinical referral/treatment thresholds.
- Describe the surgical procedures and the associated indications.
- Advise on appropriate clinical referral/treatment thresholds based on the available evidence of clinical effectiveness, cost-effectiveness and best practice.
- Consider the impact that implementation of clinical referral/treatment thresholds for scheduled surgical procedures is likely to have including resource and budget impact and wider ethical or societal implications as appropriate.

HTA is a management and decision support tool used to inform objective decision making. The specific remit of this assessment is as a 'rapid HTA'. The term 'rapid HTA' is analogous to that of a 'mini-HTA'; both terms are widely used in the international HTA setting to refer to a HTA with restricted research questions whose purpose is to inform decision making in a particular service setting or for a specific group of patients. Based on the approach used in a full HTA assessment, a rapid HTA uses a truncated research strategy with the review of published literature often restricted to a review of the secondary literature (including systematic reviews, meta-analysis, guidelines etc.) and does not include development of an independent economic model. This approach is useful when undertaking assessments that are proportionate to the needs of the decision maker.

1.3 Overall approach

Following an initial scoping of the issue, the Terms of Reference of this assessment were agreed between the Authority and the Health Service Executive (HSE).

The Authority convened an expert advisory group (EAG) comprising representation from relevant stakeholders including clinical specialists, general practitioners, nurses, representatives of patients' organisations, and HSE and Department of Health senior managers charged with service planning and delivery. The role of the EAG is to inform and guide the process, provide expert advice and information and to provide access to data where appropriate. A full list of the membership of the EAG is available in the acknowledgements section of this report. The Terms of Reference of the EAG are to:

- Contribute to the provision of high quality and considered advice by the Authority to the Health Service Executive.
- Contribute fully to the work, debate and decision-making processes of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues outside of group meetings, as requested.
- Provide advice to the Authority regarding the scope of the analysis.
- Support the evaluation team led by the Authority during the assessment process by providing expert opinion and access to pertinent data, as appropriate.
- Review the project plan outline and advise on priorities, as required.
- Review the draft report from the evaluation team and recommend amendments, as appropriate.
- Contribute to the Authority's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment.

The Authority has appointed an evaluation team comprising of internal staff from the HTA directorate to conduct the assessment.

The Terms of Reference of the assessment were agreed by the EAG at the initial meeting of the group. Interim findings from the assessment and issues to be addressed were discussed at subsequent meetings.

A wide range of procedures were identified in the scoping phase of the assessment to which clinical referral or treatment thresholds could apply (see Section 1.4 below). Each of these procedures was considered important. Rather than delay completion of the report until all identified procedures had been assessed, it was considered prudent to develop the report on a phased basis.

To ensure efficient use of the time of EAG members, selected procedures were grouped by their clinical specialty and then assessed on a phased basis. Following review by the EAG, draft reports for each of the procedures were made available for broader consultation. Feedback was sought and obtained by open consultation through the Authority's website and through targeted consultation with key stakeholders in the area. Draft reports prepared for each phase of the project are reviewed and approved by the Executive of the Authority prior to submission to the HSE and the Minister for Health.

1.4 Identification and selection of procedures

To identify scheduled surgical procedures to which it may be appropriate to apply clinical referral or treatment thresholds, a preliminary review was undertaken of the international literature including a specific review of services provided by publicly funded healthcare systems in other countries.

Table 1.1 outlines some of the international healthcare systems that were reviewed and provides an example of the types of approaches used to develop clinical referral or treatment thresholds for scheduled surgical procedures.

Table 1.1 International approaches to the development of clinical referral/treatment thresholds

Country	Example of Approaches Used
UK	▪ **NICE** – Clinical Guidelines and Interventional Procedure Guidance (IPG) ▪ **SIGN** – Clinical Guidelines e.g. management of sore throat and indications for tonsillectomy ▪ **Quality Improvement Scotland** – evidence notes e.g. tonsillectomy for recurrent bacterial tonsillitis ▪ **NHS Primary Care Trusts (PCT)** – evidence-based thresholds
US	▪ **RAND/UCLA Appropriate Use Criteria** that combine scientific literature and expert opinion to generate 'appropriateness statements' - Topic selection: procedure widely and frequently used, consumes significant resources, has wide geographical variation in use, or substantial morbidity / mortality. - Do not assess procedures identified as 'recommended against use' by the American Academy of Orthopaedic Surgeons clinical practice guidelines. ▪ Clinical Utilisation Management Guidelines (e.g. Bluecross Blueshield): guide coverage decisions
New Zealand	**Clinical Priority Assessment Criteria** to assess benefit expected from elective surgical procedures
Western Canada	**Waiting List Project.** Prioritise access to service on the basis of need and potential benefit. Use of physician scores to measure patient priority level (cataract, hip and knee replacement, MRI scan etc)
Australia	**Institute of Health and Welfare.** Clinical urgency categorisation for elective surgery patients
Italy	**Urgency Categories** to manage elective surgery waiting lists
Holland	**Dutch Institute for Healthcare Improvement.** Evidence-based guidelines for clinical decision making.

Although all approaches were considered, specific attention was given to the National Health Service (NHS) in the UK due to the commonality between the healthcare systems, similarities in the populations, the broad recognition in Ireland of clinical guidelines developed by the UK's National Institute for Health and Care Excellence

(NICE), and the link between many professional surgical associations within the island of Ireland or between the UK and Ireland.

The use of thresholds by Primacy Care Trusts (PCT) in the UK NHS has been common practice for several years. The UK Audit Commission has estimated that approximately 250 procedures of 'limited clinical value' have been identified, with some PCTs having stated thresholds for over 100 procedures.[6] One system of categorising procedures developed by Croydon PCT uses a fourfold classification system: effective procedures where cost-effective alternatives should be tried first; effective interventions with a close benefit to risk balance in mild cases; potentially cosmetic interventions; and relatively ineffective procedures.[6] Although PCT lists vary, approximately 80 procedures were identified that were common across the majority of lists. The procedures identified from the review of international practice were assessed for their relevance to the publicly funded healthcare system in Ireland. Data were obtained from two main sources: the Hospital In-Patient Enquiry (HIPE) system and from the National Treatment Purchase Fund (NTPF).

HIPE is a computer-based system that collects demographic, clinical and administrative data on discharges and deaths from acute public hospitals participating in the scheme (n= 57 in 2011).[7] Activity levels from the HIPE system were retrieved for each procedure type with data gathered in respect of the total number of procedures undertaken (and broken down by day case and inpatient surgery), the average length of stay (ALOS) and total number of inpatient bed days consumed by inpatient surgery. Data were collected for 2011 and compared to activity levels in previous years to provide an estimation of trends in clinical practice.

Surgical procedures were identified by their ICD-10 AM procedure codes (International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification).[7] These codes were collated from a number of sources and also by cross-referencing the ICD-10 manual against the OPCS-4 classification system used for procedures and surgical operations in the UK.[8] Cross-referencing of the OPCS-4 and ICD-10 codes was undertaken, where possible, to ensure that the stated thresholds were for comparable procedures.

The average cost-per-case for inpatient and day case surgery was obtained from the 2013 'Ready Reckoner' published by the National Casemix Programme.[9] This reports the inpatient and day case activity and costs for the 38 hospitals that participated in the National Casemix Programme in 2011. Cases were classified into DRGs (diagnosis-related groups) based on the primary ICD-10 procedure code assigned to the case.

The NTPF was set up in April 2002 as an initiative of the Health Strategy and Programme for Government. The role of the fund is to reduce the time public

patients wait for operations on public hospital waiting lists. This was initially achieved primarily by procuring additional surgical capacity in private hospitals in Ireland, Northern Ireland and England. As a result of a significant policy change in July 2011, however, the NTPF is now primarily used to support public hospitals to provide this additional surgical capacity.[10] Surgical activity outsourced to private hospitals and abroad is not captured by HIPE and was therefore obtained directly from the NTPF.

The NTPF also operates the national Patient Treatment Register (PTR). This register collects waiting list information on an individual patient basis for surgical and medical inpatient and day case waiting lists from all public hospitals in Ireland. PTR data were obtained for September 2012: at that time 49,601 patients were on the waiting list for over 100 medical and surgical procedures, 86% of whom were on the waiting list for less than six months. A number of surgical procedures accounted for a large number of those waiting, including: cataract surgery (n=3,805), dermatological excision of skin lesions (n=3,704), orthopaedic procedures such as arthroplasty and arthroscopy (n=2,829), tonsillectomy (n=1,448) and varicose vein surgery (n=928).[11]

Data retrieved from the HIPE system were grouped by the clinical speciality (e.g., ophthalmology, orthopaedics, vascular). These were compared with the PTR data and with the list of procedures identified from the review of international practice for which thresholds may be relevant. A list of procedures was developed for each surgical discipline. These were reviewed by the Expert Advisory Group, and a refined list of procedures to be assessed was developed. Procedures were assessed on a phased basis according to the surgical discipline as outlined in Section 1.3. Included in Phase I were: cataract surgery, tonsillectomy, adenoidectomy and grommet insertion, and varicose vein surgery.

1.5 Assessment of selected procedures

A stand-alone chapter was developed for each surgical procedure selected for assessment. The surgical indication is detailed and a brief review of the procedure, its potential complications and the alternatives to the procedure is provided. Current practice in Ireland is described including the data outlined in Section 1.3 from HIPE, the NTPF, PTR and the National Casemix Programme. Also detailed are data from the HSE's Outpatient Data Quality Programme. This programme was developed in January 2011 in order to obtain standardised, defined and robust data relating to consultant-delivered outpatient services and to improve the quality of the processes used by acute hospitals to manage their demand for outpatient services.[12] This new minimum dataset comprises validated data on the number of referrals by clinical specialty, the number of attendances, the ratio of return to new patients, non-

attendance rates (did not attends) and waiting times. As previously stated, this data is not complete as not all hospitals are currently reporting, however, the data is now of sufficient volume and quality that public reporting has started. Data on each of these metrics is included as appropriate in the assessment for each of the surgical disciplines.

To support the assessment of each procedure, a comprehensive review of the literature was conducted to identify international clinical guidelines, health policy documents describing treatment thresholds that are in place in other health systems and economic evaluations for that procedure. The approach and general search terms are described in Appendix 1. A summary of the main results of each of these searches is included in the relevant chapters along with a summary of the potential budget impact and resource implications of a threshold. Each chapter concludes with advice on the recommended referral/treatment threshold and a discussion of this advice including the potential ethical or societal implications of stated thresholds.

References

(1) Central Statistics Office. *2011 Census Results*. Ireland: Central Statistics Office; 2011.

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(7) Hospital In-Patient Enquiry. *Hospital In-Patient Enquiry (HIPE) Portal data*. Ireland: ESRI; 2013.

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(9) National Casemix Programme. *Ready Reckoner of Acute Hospital inpatient and daycase activity and costs (summarised by DRG) relating to 2011 costs and activity*. Ireland: Health Service Executive; 2013.

(10) National Treatment Purchase Fund (NTPF). *Minister announces changes in role of the NTPF to support the Special Delivery Unit. Press Release: Monday 28th July 2011* [Online]. Available from: http://www.ntpf.ie/news/PressRelease_20110728.asp. Accessed on: 2 January 2013.

(11) National Treatment Purchase Fund (NTPF). *Hospital elective surgery waiting list data (September 2012).* Ireland: NTPF; 2012.

(12) Health Service Executive. *Outpatient Data Quality Programme Update February 2012* [Online]. Available from: http://www.hse.ie/eng/services/Publications/corporate/performancereports/Outpatient_Data_Quality_Programme.pdf. Accessed on: 24 January 2013.

Appendix 1 Search Strategy

Literature searches for clinical guidelines, reviews of clinical effectiveness, thresholds used in other health systems and cost-effectiveness analyses were conducted using the strategy outlined below. A separate list of search terms was used to define each indication (including relevant synonyms and related terminology).

1.1 Search strategy for clinical guidelines

Searches for relevant clinical guidelines were conducted in the information resources listed in Table App1.1 below.

Table App 1.1 Summary of information sources reviewed

Name	Geographical Focus	Link	Filter
CMA Infobase	Canada	http://www.cma.ca/index.php/ci_id/54316/la_id/1.htm	None
NHS Evidence	UK	http://www.evidence.nhs.uk/	None
NICE	UK	http://www.nice.org.uk/	None
SIGN	Scotland	http://www.sign.ac.uk/	None
NZ Guideline Group	New Zealand	http://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group	None
ANHMRC	Australia	http://www.nhmrc.gov.au/guidelines	None
TRIP	International	http://www.tripdatabase.com/	"Keywords(clinical guideline*;practice guideline*;clinical practice guideline*;standard*;consensus statement*;consensus protocol*)"
PubMed	International	http://www.ncbi.nlm.nih.gov/pubmed	GL Filter – Publication Type(Consensus development conference; guideline; practice guideline)
GIN	International	http://www.g-i-n.net/	None
NCEC	Ireland	http://www.patientsafetyfirst.ie/index.php/national-clinical-effectiveness-committee.html	None
RCSI	Ireland	http://www.rcsi.ie/	None
US National Guideline Clearinghouse	USA	http://guideline.gov/	None

1.2 Search strategy for referral / treatment thresholds

Policy documents and other sources of information on treatment thresholds for individual indications that had been developed in other national health systems were carried out by searching the websites of health departments of relevant countries. This included searching the websites of UK primary care trusts (PCTs) and organisations that had contributed to guidelines' development. The search was restricted to English language resources.

1.3 Search strategy for reviews of clinical effectiveness

Reviews of clinical effectiveness were identified by searching the Cochrane Library and the databases of the Centre for Reviews and Dissemination (CRD). PubMed was also searched using the publication type filter for meta-analyses and reviews.

Cochrane library databases	Systematic Review Database
	HTA Database
CRD Databases	Database of abstract of reviews of effects
	HTA Database
PubMed	Meta-analysis and review filter used

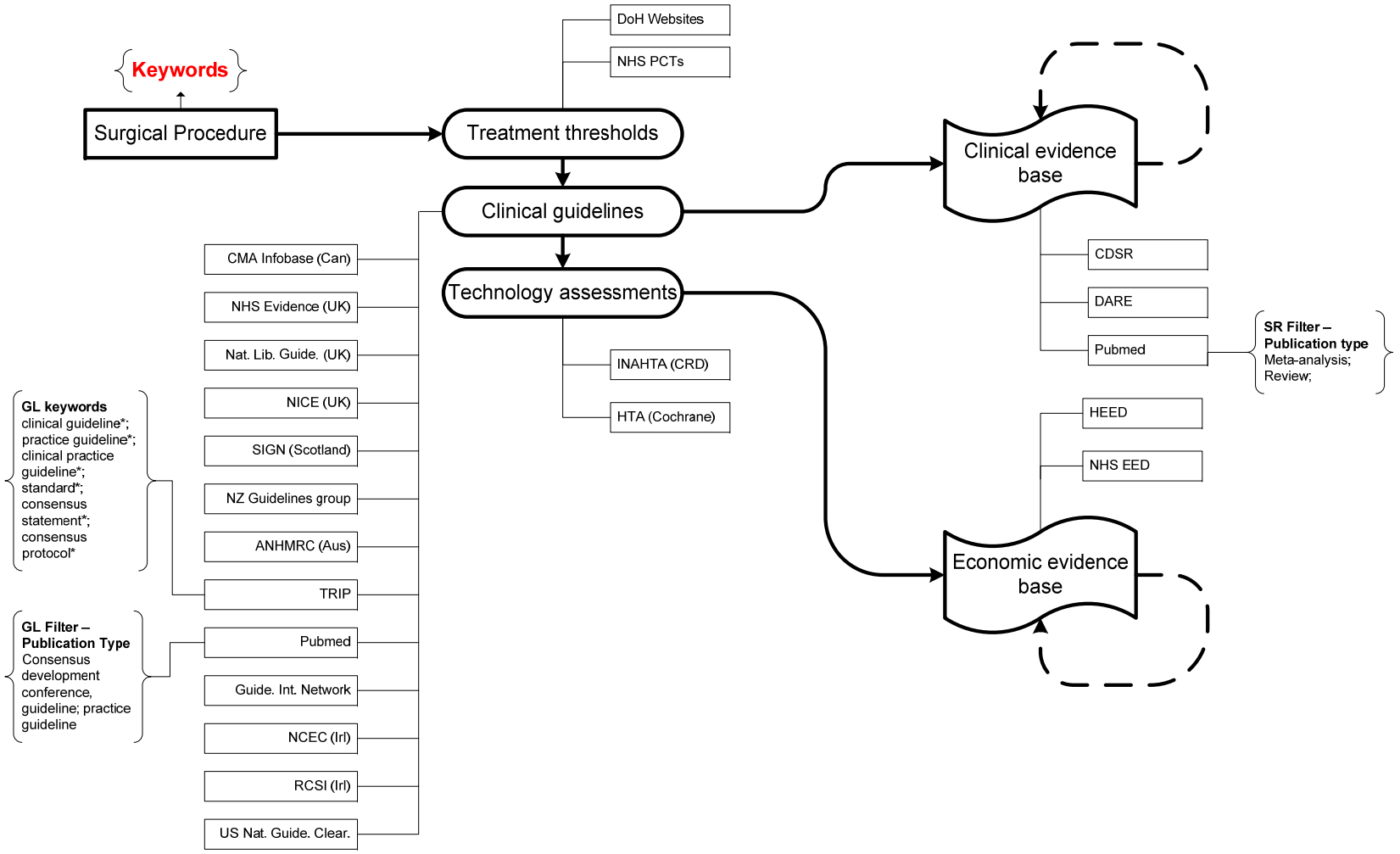
Reference lists from clinical guidelines that had been previously identified were also reviewed.

1.4 Search strategy for studies of cost-effectiveness of thresholds

Studies examining the cost-effectiveness of threshold introduction or other relevant issues in relation the procedure under review were identified by searching the NHS Economic Evaluation Database (NHS EED, via the Cochrane Library) and the Health Economic Evaluation Database (HEED, via the Wiley online library).

A flowchart showing the overall search strategy is provided in Figure app1.1.

Figure App 1.1 Search strategy flowchart



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