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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Evidence Standards Framework for Digital Health Technologies

Cost Consequences and Budget Impact Analyses and Data Sources

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Contents

Abbreviations

A&E	Accident and Emergency
BIA	Budget impact analysis
CCA	Cost-consequence analysis
CCG	Clinical commissioning groups
CUA	Cost utility analysis
DHT	Digital health technology
DSA	Deterministic sensitivity analysis
HRG	Healthcare Resource Group
NICE	National Institute for Health and Care Excellence
NPV	Net present value
ONS	Office of National Statistics
PHE	Public Health England
PSA	Probabilistic sensitivity analysis
PSS	Personal social services
QALY	Quality-adjusted life year
VAT	Value added tax
YHEC	York Health Economics Consortium

Section 1: Introduction

1.1 DOCUMENT PURPOSE

This document explains the two main forms of economic analyses specified by the National Institute for Health and Care Excellence (NICE) in its evidence standards framework for a digital health technology (DHT). It has been commissioned by NICE as 1 of a range of supporting resources. The document:

- Describes the principles of cost consequences analysis (CCA) and budget impact analysis (BIA) (Section 2)
- Provides some sources of reliable information on epidemiology, clinical pathways, resource use and unit costs, all freely available, to assist users in selecting appropriate parameters for economic models (Section 3).

The aim of providing this information to DHT developers building, or commissioning others to build, models to submit for evaluators, including commissioners, is to reduce uncertainties on CCA models and how to use the information from such a model to inform a BIA.

1.2 CONTEXT

In March 2019, NICE published an evidence standards framework for DHTs. These were developed by NICE, in collaboration with NHS England, Public Health England and MedCity and finalised following a period of comment and feedback.

The framework comprises:

- Evidence for effectiveness standards and
- Evidence for economic impact standards.

The effectiveness standards framework has a different approach to classifying DHTs to that used to inform the economic impact standards. Hence it is only described briefly. The effectiveness framework adopts a functional classification system, enabling each DHT developer to identify the function delivered by their DHT. The functions are stratified into evidence tiers based on the potential risk to users. The evidence level needed for each tier is proportionate to the potential risk to users presented by the DHTs in that tier. However, even within a functional group, different DHTs may present specific risks based on their intended use. Contextual questions help identify potentially higher-risk DHTs. Best practice evidence standards in each relevant evidence tier should be used for DHTs that present a potentially higher risk to users.

The economic impact standards framework adopts 3 different levels of economic analysis Less mature DHTs require a basic economic analysis level. For more mature DHTs the level of economic analysis needed depends on several factors including:

- Stage in the life cycle of the DHT
- The value proposition of the DHT
- Strength and quality of the evidence for effectiveness
- Strength and quality of the economic evidence available
- Potential financial and organisational impact of the technology
- Total cost to the payer for the estimated user population for the proposed length of use (including the upfront cost of the DHT, implementation, training, operation and maintenance costs).

For technologies which present a low financial commitment a CCA should be conducted. For technologies which present a high financial commitment and with health outcomes funded by the NHS and Personal Social Services, a cost-utility analysis (CUA) should be adopted using NICE's guide to the methods of technology appraisal as a reference case. For DHTs with a high financial risk which have non-health outcomes, a CCA may be used. For DHTs funded by the public sector with health and non-health outcomes, or for DHTs that focus on social care, a CCU should be done if possible; otherwise a CCA may be acceptable. The analysis should be conducted using developing NICE guidelines: the manual as a reference case.

This approach aligns decisions on high risk DHTs with other technologies considered by NICE in its guidelines and technology appraisal programmes.

A BIA should be conducted for all DHTs. Existing NICE resource reports and templates provide examples of such analyses.

The next Section describes the principles and methods of CCA and its relationship to a BIA. It does not address CUA. This form of analysis is already widely used in the health technology appraisals conducted by, or on behalf, of NICE.

Section 2: Principles of Cost Consequences Analysis and Budget Impact Analysis

2.1 COST CONSEQUENCES ANALYSIS

Cost consequences analysis (CCA) was developed by Mauskopf *et al.* to provide an alternative approach to presenting information to decision-makers to assist them when commissioning new technologies. CCA considers all relevant health and non-health effects of an intervention, across different sectors, and reports them without aggregation. It is useful when different outcomes cannot be incorporated into a single health utility index measure.

CCA is already adopted by NICE when judging the value for money of medical technologies (see medical technologies evaluation programme process and methods guide) and in developing guidelines if an intervention to be included in a guideline will be funded in part or totally by a non-NHS public sector body, particularly if it has a social care focus and delivers non-health outcomes (see developing NICE guidelines: the manual). The new DHT is compared with current practice so the focus is on incremental costs and benefits.

All material outcomes should be considered in a CCA including those which cannot be monetised (that is cannot be expressed in pounds sterling). Examples of such outcomes are reduced health inequality, improved user convenience, reduced anxiety for patients or carers and higher user satisfaction. CCA encompasses all types of benefits, not just those which can be measured by a patient's health related quality of life and life expectancy. This is the key difference between CCA and CUA.

The full cost of the DHT and the comparator, over a lifetime time horizon, should also be reported. This is necessary to enable decision-makers to purchase DHTs which represent the best value. As NICE notes, effectively, cost–consequences analysis provides a 'balance sheet' of outcomes that decision-makers can weigh up against the costs of an intervention (including related future costs).

Mauskopf *et al.* judged that the CCA format is more transparent, readily understandable and easier to apply than other forms of economic analysis, such as CUAs (where incremental cost-effectiveness ratios are compared against reimbursement thresholds). CCA is also comprehensive, enabling all benefits to be considered, not just those which impact on health outcomes or those which can be monetised. For example, if a new DHT offers benefits to healthcare professionals these can always be evaluated under CCA. This is not true with other forms of economic analysis.

A well-constructed CCA enables the decision-maker to select items from the analyses to compute composite measures of value, such as cost per life-year gained or cost per quality-adjusted life-year (QALY) gained, but decisions are not limited to considering only these factors. In general, the CCA approach, by making the impact of the DHT as comprehensive and transparent as possible, will enable decision-makers to select the components most relevant to their perspective and will also give them confidence that the data are credible to use as the basis for resource allocation decisions.

2.2 CONDUCTING A CCA

The NICE evidence standards framework identifies:

- The key economic information that must be collected and used to populate an economic model
- Appropriate analysis of the data collected
- Reporting standards

This Section provides further details on these aspects.

2.2.1 CCA Economic Models

CCA models must be clinically appropriate, technically robust, populated using values taken from acceptable sources of evidence and validated for internal and external consistency. The aim of a model is to provide decision-makers with a credible representation of the likely impact of a DHT on the healthcare system over the lifetime of the DHT.

Model design can vary in complexity depending in part on the nature of the disease(s), the number of groups impacted by the DHT (e.g. different clinical teams, number of relevant patient sub-groups and wider impact on care-givers, including social care) and the availability of data to populate the model.

2.2.2 Decision Problem

Prior to designing the CCA, the decision problem that the analysis seeks to address should be specified. This should outline the following:

- Population being the user group of interest. This may be a subgroup of the overall population able to use the DHT. Where possible the population(s) should align with that included in clinical trials.
- Intervention being the DHT under evaluation.
- Comparator being current standard care within the setting of interest. It may be that there are several comparators or that the DHT is used as an adjunct to standard care.

- Outcomes to be included in a CCA. The list should contain all material cost items over the time frame, patient benefits and related factors such as compliance, adverse events related to the DHT and ease of use for relevant staff group.

Examples of published decision problems can be found in the "scope" produced for each NICE appraisal.

2.2.3 Perspective

The next step for a CCA is to be clear on the appropriate perspective of the analysis. This depends on the decision maker. Ideally, the perspective of the CCA should be aligned with the perspective of the body funding the DHT. If the NHS is commissioning the DHT, a NHS and personal social services (PSS) perspective is usually required. For public health or social care DHTs, all direct health effects for people using services or, when relevant, other people such as family members and/or informal carers can be included. It may also be valid to include non-health effects such as productivity benefits or absences from school.

When the DHT is part or wholly funded by non-NHS bodies, a wider public sector (societal) perspective, may be appropriate. This would include all costs or savings paid for, or saved, by the funders, or any arm of government. Hence it could include all tax and welfare receipts and payments. When planning to adopt a wider perspective than NHS and PSS, developers may benefit from seeking to agree this with commissioners before commencing modelling. Alternatively, where the DHT is wholly funded by a non-NHS body, for example a local health authority, it may be appropriate to take that perspective for both costs and benefits.

2.2.4 Clinical and Social Care Pathways

An informative CCA model provides a good representation of the current patient pathway and how this will change with the DHT. NICE Pathways provides many current pathways in the form of interactive tools. Some DHTs may require modifications to current pathways or indeed be disruptive and require new pathways to be developed; their development should be informed by engaging clinical teams.

The pathways should be captured diagrammatically ideally in the form of flow diagrams. The modelled pathways should capture all important heath states. These may be stages in a diagnostic pathway or in a disease's progression. Some models may have no health states e.g. if the DHT improves system efficiency and does not impact on patient outcomes.

Three examples of the pathways used in models developed by York Health Economics Consortium (YHEC) in projects are provided at Appendix A.

2.2.5 User Population

The CCA model should report the relative impact of the DHT for the expected number eligible for, and adopting (take-up), the DHT and current practice. Where the take-up or relative effectiveness of the DHT differs across user populations then results and sensitivity analyses should be reported for each relevant subgroup. The size of the user population may vary considerably between the DHT and usual care. For example, if current practice is structured education, delivered face to face in working hours, then a high-quality DHT, available 24/7, may have a materially higher take-up than current practice, within the eligible population.

The current NICE BIA templates are usually pre-populated with relevant national and regional populations for an array of diseases and technologies. The accompanying reports explain the methodologies adopted and assumptions used to derive these estimates.

2.2.6 Capturing Resource Use and Patient Outcomes

The CCA model should be constructed such that all material resources required to process patients through each pathway are captured. Examples include staff mix and staff time, number of tests, investigations, procedures, hospital admissions, inpatient days, outpatient appointments, primary care attendances and social care packages. Each health state is normally associated with the resources used when patients are in it.

The evidence linking the use of the DHT to the estimated changes in resource use should be robust and well described. This is challenging unless the developer has high-quality evidence of effectiveness or resource use from a clinical study. Where such evidence is lacking, scenario analysis can show the impact on the CCA results associated with the uncertainty in the effectiveness data. Resource use data may be obtained from relevant published evidence obtained via a literature review.

Some resources required may sit outside the pathways, specifically those incurred by commissioners or providers to acquire and implement the DHT. These include any associated infrastructure, change in existing working practices and training required to implement the DHT. Moreover, annual operating items such as consumables, repair and maintenance of the DHT and licences and warranties should also be included in the model.

The impact on patient outcomes is also required. These are also associated with each health state adopted in each pathway. Typically, several outcomes are used, being the clinical events themselves, such as the number of strokes or cancers avoided, and the associated impact on life expectancy and health-related quality of life for patients. Change in health outcomes will be linked to changes in resource use. For example, a reduction in the number of strokes will reduce the number of hospital admissions, procedures, inpatient days, GP appointments, care home placements and social care packages.

Ideally the developer will also have high-quality evidence of the impact of the DHT on patient outcomes from a clinical or patient reported outcomes study. If not, a well-conducted literature review may identify the patient outcomes reported in previous studies for the health states and the patient groups included in the model.

Finally, developers may also want to measure the impact of the DHT on users, (for example, benefits to operators in terms of ease of use or increased accuracy with the DHT, which are additional to time savings). These may be informed by qualitative analyses.

2.2.7 Unit Costs

Where possible the value of each resource used or released should be reported by applying relevant unit costs to the estimated resource use. Potential sources of unit costs are provided in Section 3. Further, where NICE has produced guidance on a related disease area or technology this may be accompanied by an estimate of the costs or savings (budget impact) using a resource impact template and accompanying report.

2.2.8 Discounting

The Treasury requires that the costs and benefits of all projects undertaken in the public sector are adjusted onto a common "present value" basis. This enables them to be compared and ranked.

Hence, CCA models should discount future costs and benefits to determine their net present value (NPV), over the appropriate lifetime at the annual discount rate set by the UK Treasury (currently 3.5%). If the NPV is positive, that means that the value of the revenues (cash inflows) is greater than the costs (cash outflows).

The formula to use is: Discounted NPV = $\frac{(\text{Cost} - \text{savings})}{(1 + i)^n}$

Where i = annual discount rate (3.5%) and n is number of years from start of project. Note Excel has a function to undertake discounting.

As an example, if a DHT costs £5,000 in current year and saves £1,100 a year for 5 years, starting from the installation period, then the model should calculate the discounted NPV of £140 as shown in Table 2.1. With no discounting, the savings are £500.

Table 2.1: Worked example of discounted NPV

Year	Costs	Savings	Net cash flow	Discount factor	Discounted net cash flow
1	-£5,000	£1,100	-£3,900	1	-£3,900
2		£1,100	£1,100	1/1.035	£1,063
3		£1,100	£1,100	$1/1.035^2$	£1,027
4		£1,100	£1,100	$1/1.035^3$	£992
5		£1,100	£1,100	$1/1.035^4$	£959
Total	**-£5,000**	**£5,500**			**£140**

Note the costs and savings set out in a BIA should not be discounted.

2.2.9 Model Validation and Transparency

Decision-makers require assurance that they can have confidence in the results of a CCA model. This requires that developers:

- Describe the model structure, choice of input parameters and all assumptions used and acknowledge its limitations. This must be in sufficient detail, using nontechnical language, so that decision-makers can understand what the model does and does not do.
- Validate the model. This involves internal validity (check accuracy of calculations), cross validity (comparison of results with other models analysing the same problem) and external validity (comparing model results with real-world results).

More detail on these steps is provided by ISPOR.

2.2.10 Reporting the Results from CCA Models

Table 9 of the NICE evidence standards framework sets out the approach developers are recommended to adopt when reporting a CCA or CUA analysis. Mauskopf et al. provides an example of a CCA table, whilst the UroLift case study presents an example of how a device developer has completed the CCA section of the NICE "Sponsor submission of evidence: template for the Medical Technologies Evaluation Programme".

The key differences with CCA, compared to any other form of economic analysis are it requires developers to:

- Tabulate all benefits, identifying their monetary value where possible, together with the sum thereof, for the DHT and its comparator
- Tabulate all costs and provide totals for the DHT and its comparator
- Calculate incremental benefits and costs

Where possible benefits and costs should be reported in terms of natural units, unit cost and total cost. Benefits and costs are not combined into a single ratio.

2.2.11 Sensitivity Analyses

As a minimum developers must conduct and present the results of deterministic one-way sensitivity analysis (DSA) of the key variables. DSA informs users of the sensitivity of the modelled results to variations in a specific input parameter or a set of parameters. One or more parameters are manually changed (usually across a pre-specified range) and the results are analysed to determine to what extent the change has an impact on the output values. The range of variation of each parameter is usually pre-specified, and where appropriate it corresponds to the uncertainty in that parameter reported in source studies, (for example, 95% confidence interval for efficacy from a source trial or meta-analysis).

Some developers may wish to conduct probabilistic sensitivity analysis (PSA). PSA quantifies the level of confidence users can have in the output of the analysis, in relation to uncertainty in the model inputs.

Scenario analyses can be useful to model alternative scenarios including different patient populations and DHT use in difference settings to consider the impact of regional and local differences in pathways. For example, a new DHT to improve wound care dressing may be used on patients in the community or as day cases or following an inpatient admission. Each setting may have a different clinical pathway, comparator, resource use and potential savings associated with the DHT. These can be captured using different decision trees – with one tree for each setting.

2.2.12 More Information on Economic Modelling

Fuller information on the appropriate perspective, resources and the approach to value resources using relevant unit costs is available in section 5 of the guide to the methods of technology appraisal and section 7 of developing NICE guidelines: the manual.

2.3 BUDGET IMPACT ANALYSIS

The NICE evidence standards framework requires developers to provide commissioners with a BIA to inform a comprehensive economic assessment of a DHT. The aim of a BIA is to give an estimate of the impact of the DHT on the decision-maker's budgets, usually over the next 5 years, with a 1 to 2-year period, being sufficient for DHTs requiring a basic level economic analysis.

The key elements of a BIA are similar to those for a CCA including estimating the size of the eligible population, current and future patient pathways, changes in resource use and the costs thereof. Sensitivity analyse are also required. The reporting of a BIA is also similar. For each cost or benefit item, the number of resources required or saved, and their unit costs should be reported, together with the item's cost. The totals for all cost items and benefits which are monetised should be provided, together with the incremental cost or saving.

The key differences are:

- BIA only considers costs and benefits which are monetised; non-financial benefits are not included in a BIA.
- A BIA includes any value added tax (VAT) payable, as a separate cost component, unlike the unit costs applied within a CCA.
- No discounting is undertaken of costs and benefits in future years.
- The perspective is usually that of the budget holder/commissioner which may be narrower than that used in CCA.

- Total costs are reported, unlike CCA where a cost per patient or per user may be preferred for comparison purposes.

It is important that the BIA uses the same populations, measures of effectiveness, resource and unit cost (ex-VAT price) assumptions as the CCA. The two sets of assumptions must be consistent, otherwise commissioners will not trust either analysis. Further guidance on BIA is available from ISPOR. Whilst written from a pharmaceutical perspective it is as relevant to DHTs.

Section 3: Epidemiology and Cost Sources

This Section provides links to sources of national data providing information on epidemiology, and volumes and unit costs of NHS and social care activities in England, as at January 2019. Please note that this list is not exhaustive and developers must take responsibility for identifying and validating relevant data inputs.

3.1 USEFUL WEBSITES

Useful websites include:

The NICE website, particularly for clinical pathways; estimates of populations, resource and costs used in health technology assessments from resource impact templates; methodological guides on the reference cases to adopt in CCA and CUA models and existing guidance. The Guidance and advice list reports all guidance and advice published or in development by topic.

The NICE Evidence Search provides access to selected and authoritative evidence in health, social care and public health.

The NICE CKS summaries the current evidence base and provides practical guidance on best practice in respect of over 330 common and/or significant primary care presentations.

The NICE Evidence Services provide access to authoritative evidence and best practice on a rage of interventions and treatment.

NICE has also published return on investment excel models and videos on:

- Tobacco
- Alcohol
- Physical Activity
- Social and emotional wellbeing
- Children, young people and pregnant women

The Public Health England (PHE) website has official statistics on general public health and disease specific which are listed here. The PHE website also has data and analysis tools and resources. These cover over a wide range of public health areas including:

- Specific health conditions – such as cancer, mental health, cardiovascular disease.
- Lifestyle risk factors – such as smoking, alcohol and obesity.
- Wider determinants of health – such as environment, housing and deprivation.
- Health protection, and differences between population groups, including adults, older people, and children.

PHE has developed also developed 2 e-learning modules, which provide an introduction to basic health economics.

It has produced interactive tools on diseases including:

- NHS Diabetes Prevention Programme
- Weight management
- Mental health service
- Cardiovascular disease

It provides a summary of economic evidence underpinning public health interventions. It has also created a PHE Video: What health economic tools and resources have PHE made available? and Who do we need to influence when making the case for investing in prevention.

NHS Digital publishes data and information from across the health and social care system in England, including over a thousand health and social care indicators in England. The full list of publications is available here.

NHS England's publications include:

- Statistics on a range of health and care subjects, with a full list here.
- Produced in conjunction with NHS Improvement the National Tariff framework and the tariffs themselves.
- The six National Programmes of Care are internal medicine, cancer, mental health, trauma, women and children, blood and infection. Each is broken down into clinical reference groups. Each clinical reference group has service specifications and standard contracts, which provide epidemiology data and cost of illness information.
- Its Specialised Services Quality Dashboards which are designed to provide assurance on the quality of care by collecting information about outcomes from healthcare providers.
- Resources to assist in modelling demand and capacity.
- An A to Z of topics covered on their website.

NHS Improvement publishes NHS Reference Costs which has national cost data. It also has documents relating to finance and resource use and re-designing pathways.

The Office for National Statistics (ONS) publishes a range of statistics from birth to death and its causes and includes information on life expectancy and years of good health. Statistics are also available on a range of disease and conditions, as described here.

3.2 POPULATION ESTIMATES

Population estimates for England are available from the Office for National Statistics (ONS).

Subnational population projections of the future size and age structure of the population in the regions, local authorities, clinical commissioning groups (CGC) and NHS regions of England are also available from ONS.

General Practitioner (GP) registered populations are available at national, CCG or GP practice level.

3.3 MORTALITY STATISTICS

Mortality statistics by cause of death are available from ONS.

3.4 INCIDENCE AND PREVALENCE DATA

Guidance and clinical guidelines published by the NICE often contain epidemiological data for disease areas.

Hospital episode statistics reports data on inpatient episodes, outpatient appointments, Accident and Emergency (A&E) attendances, maternity and adult critical care in NHS hospitals in England.

Hospital admitted patient care describes NHS-funded inpatient, day case and adult critical care activity. Data are available by CCG, diagnosis, Healthcare Resource Group (HRG), procedures and treatment speciality. The parameters are also analysed by ethnicity and deprivation status.

The Outpatient activity report presents the number of outpatient appointments, attendances, and 'did not attends' over the past financial year, broken down by age and gender.

Weekly and Monthly A&E Attendances and Emergency Admissions reports attendances for all A&E types, including Minor Injury Units and Walk-in Centres, and of these, the number of patients discharged, admitted or transferred within four hours of arrival. Data are reported for NHS Trusts, NHS Foundation Trusts and Independent Sector Organisations.
Prevalence and quality data for a number of common chronic diseases, public health measures and preventative screening data are available from Quality and Outcomes Framework.

Key national patient organisations often have incidence and prevalence data available on their websites. For example, Cancer Research UK has incidence, prevalence and mortality statistics on all cancer types.

The NHS Safety Thermometer reports national and regional data on patient harms, such as pressure ulcers, falls, catheters, urinary tract infections and venous thromboembolisms. Safety thermometers are also now available for medication, mental health, maternity and children & young people.

Community care statistics and social services activity describes the numbers of people receiving support in the community and the type of care received.

3.5 UNIT COSTS

NHS Reference Costs reports mean unit costs and length of stay for elective and non-elective patient stays, analysed by HRG. Information on outpatient procedures, emergency medicine, chemotherapy, critical care, diagnostic imaging and radiotherapy are also included.

NHS Tariffs for 2017/18 to 2018/19, detail the unit prices that NHS providers charge NHS commissioners for activity conducted.

Unit costs of health and social care staff are available from Personal Social Services Research Unit. This includes hourly costs for community based healthcare staff including GPs and practice nurses; hospital based staff such as consultants, ward nurses, physiotherapists and radiographers, and social care and care home costs. It also provides inflation indices for the previous ten years for hospital & community health services.

Personal Social Services Expenditure and Unit Costs contains data on the number and unit cost of patients receiving nursing or residential support for the following; physical, sensory, learning disability, memory and cognition or mental health.

NHS Supply Chain catalogue has costs and volumes for many items bought by the NHS. This is only available with an NHS log in, but one can submit a freedom of information request to gain access to specific information.

3.5.1 Medication Costs

NHS Business Services Authority shows national prescription data dispensed in the community in England.

The NHS Dictionary of Medicines and Devices database is an alternative source of information on prices. This data is supplied by the NHS Business Services Authority and is updated weekly.

Medication costs per item dispensed are also available from the British National Formulary and BNF for children.

The Department of Health provides information about prices and usage for generic drugs and pharmaceutical products in secondary care.

3.6 PATIENT REPORTED OUTCOMES

Patient reported outcome measures are available for groin hernia, hip replacement, knee replacement and varicose vein procedures.

Information on population norms values for health-related quality of life using NICE's preferred measure (EQ-5D-3L) is available on the Euroqol website. Further information is provided around using and evaluating the questionnaire.

3.7 GENERAL HEALTH DATA AND STATISTICS

The Interactive Compendium of Health Datasets for Economists provides access (where available) to over 270 health and health care related data and resources.

NHS Evidence provides a wide range of health information, from accredited bodies, including evidence on care pathways, commissioning guidelines, drug and medicines management, DHTs, devices and diagnostics, public health and social care.

National Audit Office reports findings from audits of healthcare services. Topics range from access to specific services, management of long-term conditions, specific procedures such as hip replacement and financial performance of trusts.

The Department of Health publishes annual statistics on abortion, hospital estates and facilities and other statistics as needed.

Health expectancy by age data, including years of good health are available from ONS. It also publishes data on maternity, birth, inequalities and general healthcare expenditure in the UK: http://www.ons.gov.uk/ons/taxonomy/index.html?nscl=Health+Care+System

NHS Workforce statistics shows the numbers of NHS Hospital and Community Health Service staff groups working in Trusts and CCGs and in primary care.

3.8 MISCELLANEOUS

Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. Geneva: World Health Organization; 2016. This guide presents comprehensive information in an accessible way on study design and evaluation of DHT.

Digital Health Technology and Evidence and Evidence Map. Medcity, Digitalhealth London and BSI. 2018, provides details onorganisations that support SMEs to generate evidence for adoption into the NHS.

Section 4: Glossary

This section includes a glossary of health economic terms that uses terms and definitions from the NICE medical technologies evaluation programme process and methods guide, NICE's guide to the methods of technology appraisal and the York Health Economics Consortium glossary of health economic terms.

Adherence	The extent to which a person follows the health advice agreed with healthcare professionals. It may also be referred to as 'compliance'.
Adverse effect	A consequence other than that which was intended. Adverse effects relate specifically to drugs or other treatments or interventions, including DHTs that a person is receiving – they are a toxic reaction.
Assessment report	A report produced by one of NICE's independent External Assessment Centres that reviews the sponsor's evidence submission and may include additional analysis of the submitted evidence or new clinical and/or economic evidence.
Baseline	Used to describe the initial set of measurements taken at the beginning of a study (after a run-in period, when applicable).
Case for adoption	The clinical and cost benefits that would be realised if the technology were taken up in place of the best available alternative.
Clinical trial	A clinical trial is a research investigation in a clinical setting, designed to supply data on, for example, the efficacy and/or safety of a drug, device, treatment or other healthcare issue. Clinical trials may be sponsored by a governmental organisation, an academic research institute, a non-governmental organisation such as a charity or a manufacturer. A trial can be conducted only after safety and ethics approval have been granted in the relevant country. Trials may involve healthy volunteers or patients, and their size should be determined by power calculations. Clinical trials are recorded in a variety of databases including ClinicalTrials.gov (USA), the European Union Clinical Trials Register, and a range of national databases accessed by the World Health Organisation International Clinical Trials Registry Platform.
Clinical utility	The clinical usefulness of a technology. For example, the clinical utility of a diagnostic test is its capacity to rule a diagnosis in or out, and to help make a decision about adopting or rejecting a therapeutic intervention.
Comparator	The standard technology against which the technology under evaluation is compared. The comparator is usually a similar or equivalent technology used as part of current management. The comparator can be no intervention, for example best supportive care.
Confidence interval	A range of values for an unknown population parameter, (for example, blood pressure) with a stated 'confidence' (conventionally 95%) that it contains the true value. The range is calculated from sample data, and generally includes the sample estimate. The 'confidence' value means that if the method used to calculate the interval is repeated many times, then that proportion of ranges will actually contain the true value.
Cost analysis	A comparative evaluation of the costs and resource use consequences of two or more interventions.
Cost–benefit analysis	An economic evaluation that expresses both costs and outcomes of an intervention in monetary terms. Benefits are valued in monetary terms using valuations of people's observed or stated preferences, such as the willingness-to-pay approach.
Cost-consequence analysis	A comparative evaluation of the costs and resource use consequences of two or more interventions considered alongside the relevant clinical benefits.

Cost minimisation	Form of economic analysis which compares the costs of comparative interventions which have equivalent clinical effectiveness and safety effects. This type of analysis can be used to determine which intervention provides the least expensive way of achieving a specific health outcome.
Cost-effectiveness analysis	Form of economic analysis in which consequences of different interventions are measured using a single outcome, usually in 'natural' units, (for example, life-years gained, deaths avoided, heart attacks avoided, or cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.
Cost utility analysis	Form of economic analysis which presents results as the ratio between the incremental cost of a health-related intervention and the incremental benefit it produces in terms of the number of years lived in full health by the beneficiaries
Critical appraisal	Critical appraisal is the process of systematically assessing a piece of research, (for example, a systematic review) in terms of the validity of its methods, and how far the interpretation of the results reflect the results. Critical appraisal can be performed on any type of research output and a number of checklists are available to guide the process (See http://www.cebm.net/).
Cycle length	Cycle length only applies to Markov models and is the period between progressions across disease states. Thus with an annual cycle patients remain in the same health state for 12 months, at which time they can transition to different health states.
Data extraction	Data extraction is the process of retrieving relevant information and data from a data source. In systematic reviewing, data can come from a range of sources including both published and grey literature. The data extraction form is designed to capture the information of interest in a structured and systematic way allowing easy manipulation and analysis at later stages of the review.
Database search	A database search is a query created and performed in one or more databases so as to retrieve studies relevant to an information need. Searches need to adapt to the differing functionality and search syntax which feature in separate databases. Searching using subject headings and text words is usually supported. Complex search queries can be created using word truncation, phrase searches, word adjacency, limits (such as date or publication type) and using Boolean terms.
Decision problem	The decision problem describes the proposed approach to be taken in the sponsor's submission of evidence to answer the question in the scope. This includes the population, intervention, comparator(s), outcomes, cost analysis, subgroup analysis and any special considerations.
Decision tree	A decision tree is a form of analytical model, using distinct 'pathways' to model the potential outcomes for a patient, or group of patients. Usually, a decision tree involves a series of 'nodes' which branch out into different possible outcomes. Each node may take the form of a 'choice' (a decision about which intervention to use) or a 'probability' (an event governed by chance). Costs and outcomes are assigned to various points along each branch. Decision trees are usually used to model interventions that have distinct outcomes that can be measured at a specific time point.
Deterministic sensitivity analysis	Deterministic sensitivity analysis is a method that can be used to investigate the sensitivity of the results from a model to a particular parameter or multiple parameters. One parameter, or a set of parameters, is manually changed and the results are analysed to determine if the change has had an impact on the results. Univariate sensitivity analysis describes a situation in which one parameter is varied at a time, whilst multivariate analysis describes a situation in which more than one parameter is varied simultaneously.
Discounting	Costs and benefits incurred today are usually valued more highly than costs and benefits occurring in the future. Discounting reflects society's preference for when costs and benefits are to be experienced.

Discount rate	An economic evaluation is carried out at one specific point in time, however, costs occur at different points in time, either in the present or at some point in the future. Costs that arise in the future are often valued less than present costs, and are therefore routinely discounted. NICE guidelines recommend that costs should be discounted at 3.5% per year.
Distribution	Probability distributions in statistics are often used to describe the spread of data. For example, we may know the mean age of a population, but in fact there will be a number of people whose ages fall above and below this mean value, and not necessarily in a uniform manner. Distributions around a parameter are often defined using a mean value and standard deviation for the parameter, or "shape" and "scale" parameters. Commonly used distributions in health economics include symmetrical distributions such as the normal distribution, for parameters such as population age, and skewed distributions such as the gamma or lognormal distributions, for ratios or for parameters such as costs which are non-negative. Distributions, which describe a mutually exclusive set of outcomes, such as the beta or dirichlet distributions, are often used for probabilities.
Early modelling / early model	The purposes of early economic modelling is to allow the user to determine the relative importance of different parameter inputs, in order to inform decisions on pricing, target populations and prioritisation of further research.
Economic evaluation	Economic evaluation is the comparison of aspects of different health strategies in order to aid decision-making about their future use and encompasses a number of different types of widely used and discussed methodologies. These evaluation methods incorporate a central economic strand but may also include other elements that scrutinize the consequences, such as effectiveness.
Efficacy	The extents to which an intervention is active when studied under controlled research conditions.
End point	In a research study, an event or outcome that can be measured and constitutes 1 of the target outcomes of the trial.
Epidemiological study	The study of a disease within a population, which includes defining its incidence and prevalence and examining the roles of external influences, (for example, infection or diet) and interventions on the disease.
Equivalence	An assumption that two or more technologies result in the same clinical (efficacy and safety) outcomes.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources, including randomised controlled trials, observational studies and expert opinion (of clinical professionals and/or patients/carers).
Evidence-based medicine	Evidence-based medicine is the deliberate and explicit use of the current best evidence in combination with clinical knowledge and experience when making decisions on patient care, rather than basing decisions solely on tradition or theoretical reasoning. Evidence-based medicine aims to make clinical practice more scientifically grounded (and therefore more safe, consistent, and cost effective). Writing in the British Medical Journal, Sackett et.al (1996)1 define the best evidence based medicine as "require[ing] a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice".
Evidence synthesis (meta-analysis)	A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a more precise summary estimate of the effect on a particular outcome.
Extrapolation	In data analysis, predicting the value of a parameter outside the range of observed values.
Generalisability	The extent to which the results of a study conducted in a particular patient population and/or a specific context will apply for another population and/or in a different context.

Health economics	Health economics is a field of economics focussed on analysing the economic elements of the healthcare industry in order to enable decisions to be made around the future use of health strategies including therapies, technologies and techniques. It incorporates methodologies and theories from both the health and economics fields.
Health-related quality of life	A combination of a person's physical, mental and social wellbeing.
Intermediate outcome	Outcomes that are related to the outcome of interest but may be more easily assessed within a clinical study, (for example, blood pressure reduction is related to the risk of a stroke).
Literature review	A literature review is a search and evaluation of the available literature in a subject or chosen topic area. In health economics, literature reviews are used to identify the most appropriate data and outcomes for a wide range of uses including summarising economic or clinical evaluations of a specific health intervention or identifying data inputs for consideration to use in economic modelling. There is a large spectrum of quality and scope of reviews which is dependent on the purpose and the financial and time resources available. These range from short pragmatic reviews to systematic literature reviews, which provide a more robust and comprehensive answer to the review question and which are usually required for research presented to reimbursement agencies. Some reviews may also include a synthesis of the identified data.
Markov model	The Markov model is a framework that is used in decision analysis. The model includes all possible consequences of the intervention under investigation as disease states. These disease states are mutually exclusive and so each individual can only be in one of these disease state at a given time. Individuals move between the disease states as their condition changes over time. Time is considered as discrete time periods called 'cycles'. Moving from one disease state to another is associated with a transition probability. Examples of health states that may be included in a simple Markov model for cancer include: pre-progressed; progressed and dead.
Medical technologies guidance	Guidance produced by the Medical Technologies Advisory Committee on technologies that are routed to it for evaluation. Guidance on medical technologies produced by another NICE guidance programme is referred to by a different name, such as ‘diagnostics guidance’ or ‘technology appraisal guidance’.
Meta-analysis/meta-analyses	Meta-analysis is a statistical technique for combining data from independent studies to produce a single estimate of effect. Meta-analysis can be used whenever there is more than one study that has estimated the effect of an intervention or risk factor, and the studies are sufficiently similar in terms of the participants, interventions, outcome measurements and settings, so that it reasonable to combine the results of these studies.
Modelling	Modelling incorporates clinical, epidemiological and economical evidence into an evaluation framework that enables a point estimate for a specific outcome, for example an incremental cost-effectiveness ratio, to be determined. The uncertainty surrounding this point estimate can be investigated by conducting sensitivity analysis.
Multi-way simple sensitivity analysis	Two or more parameters are varied at the same time and the overall effect on the results is evaluated.
Odds ratio	An odds ratio is a measure of the effect of an intervention. The odds ratio is the odds of an event occurring in the intervention group divided by the odds of an event in the control group. Note: odds are the number of times that an event happens divided by the number of times it does not happen within a group. An odds ratio greater than one indicates that the event is more likely to occur in the intervention group compared to the control group. If the odds ratio is equal to one, then there is no difference between the groups (i.e. the event is equally likely to occur in the intervention group and control group).

Opportunity cost	The opportunity cost of investing in a healthcare intervention is the other healthcare programmes that are displaced by its introduction. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Outcome	The measure of the possible results of treatment with a preventive or therapeutic intervention. Outcome measures can be either intermediate or final end points. See also 'Intermediate outcome'.
Parameter	A measurable or quantifiable characteristic. For example, the relative treatment effect of a technology may be a parameter in an economic model.
Parameter uncertainty	Uncertainty about the mean values of parameters, (for example, health outcomes, utilities and resource use) included in the model.
Patient expert	Acts as an expert witness to the Appraisal Committee. Patient experts have used the technology either personally or as part of a representative group. They provide a view on the risks and benefits of the technology from personal experience as a patient or carer, and an understanding of the wider range of patient and/or carer views.
Perspective	The types of costs and health benefits that are included in an economic evaluation differ depending on the perspective that is taken. The societal viewpoint is the broadest perspective, as this aims to reflect social opportunity costs. For example, it would include productivity loss arising from patients' inability to work. NICE does not generally recommend taking this perspective as it can bias against those not in work, such as people over retirement age or those not able to work due to medical reasons. The NHS perspective would consider treatment costs in terms of drug costs, resource use costs (e.g. GP visits), and costs associated with dealing with adverse events caused by treatment, for example.
Pragmatic review	A pragmatic review is one that adapts the usual systematic review process to take into consideration limited time and/or resources available. This is usually achieved by applying additional limits to the search or eligibility criteria.
Probabilistic sensitivity analysis	Probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (for example, Monte Carlo simulation).
Quality-adjusted life year (QALY)	An index of survival that is adjusted to account for the patient's quality of life during this time. QALYs incorporate changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social, and other factors) of life. Used to measure benefits in cost–utility analysis.
Quality of life	See 'Health-related quality of life'.
Randomisation	Allocation of participants in a research study to 2 or more alternative groups using a chance procedure such as computer-generated random numbers. This approach is used to attempt to ensure there is an even distribution of participants with different characteristics between groups and reduces bias and confounding.
Randomised controlled trial	A randomised controlled trial (RCT) is an experiment designed by investigators to study at least two interventions in similar groups of randomly assigned subjects. The outcomes of interest of the intervention(s) and comparator(s) are measured (e.g. efficacy or effectiveness), often with multiple follow-up, and compared, usually using a statistical methodology. RCTs are considered very important evidence in the development of any medical intervention and their data is therefore frequently identified in reviews and used in health economic modelling.
Rapid review	Rapid reviews can provide quick summaries of what is already known about a topic or intervention. Rapid reviews use systematic review methods to search and evaluate the literature, but the extensiveness of the search and other review stages may be limited.
Reference case	When estimating clinical and cost effectiveness, the reference case specifies the methods considered by NICE to be the most appropriate for the Appraisal Committee's purpose and consistent with an NHS objective of maximising health gain from limited resources.

Register	An organisation or system that facilitates and/or undertakes the collection and collation of patient about specific disease and/or treatment outcomes, and supports and/or facilitates the quality assurance and analysis of these data.
Relative risk (RR)	The number of times more likely or less likely an event is to happen in 1 group compared with another (calculated as the risk of the event in group A divided by the risk of the event in group B). The relative risk (RR) is usually expressed as the risk of the event in the intervention group divided by the risk of the event in the comparator group. In this case, an RR of less than 1 indicates that there is less risk of the event with the intervention than the comparator.
Relative treatment effect	The effect of a treatment relative to another treatment or control, for example, measured by relative risk.
Resource consequence	A resource use consequence that is not directly part of the technology but occurs because of it.
Resource use	Resource use is any data around the consumption of units of time, cost or consumables e.g. unit cost and dosage of a drug or number of GP visits for a particular disease group per month. This data is available in a broad range of literature and is utilised in economic modelling. A review of the literature for resource use may find multiple data in which case a decision is made as to which data is most suitable for use in the particular context, usually based on how similar the parameters of the source are, to how it will be used and based on an assessment of its quality.
Scenario analysis	Scenario analyses change the combination of parameters used in the base case to reflect regional or local differences in pathways or resource use. Using the results from local scenarios to inform recommendations, in addition to those representing a national average should ensure that recommendations are robust to local variation.
Search filter	A search filter is a ready-made search strategy designed to limit search results to a set of references with specific characteristics. Filters are usually combined with a topic by using 'AND', in order to restrict the search to a smaller, more relevant set of results. For example a randomized controlled trials filter should retrieve only those studies which are RCTs. Several versions of a filter may exist depending on how exhaustive or precise they aim to be. Well-designed filters will retrieve all relevant studies while reducing the amount of literature that needs to be screened by reviewers.
Search strategy	A search strategy is a query used to retrieve information, usually from a bibliographic database. It can refer to the query used in one database, or to the general approach that is adapted for use in a number of different sources. The latter is described in the methodology sections of scientific papers. To aid the description all the proposed sources are listed. The complete database searches (or sample) can often be found as an appendix item. Search strategies vary in terms of their complexity, the range of sources used and publication types they aim to retrieve. Additional retrieval methods should be documented, including handing searching particular publications, citation searching, and expert advice.
Sensitivity analysis	Sensitivity analysis is a method used to illustrate and qualify the level of confidence in an economic evaluation's conclusions. Sensitivity analysis usually evaluates the impact of varying the numerical input for specific model parameters. It is presented in a range of forms, including one-way sensitivity analysis (where one parameter is varied individually), multi-way sensitivity analysis (where more than one parameter is varied at once), threshold analysis (where the model assesses the tipping point where an evaluation's conclusion changes) and probabilistic sensitivity analysis (where distributions are assigned to each input and a stochastic approach is taken to produce a large number of unique iterations, each producing a specific model outcome). Sensitivity analysis is vital part of the evaluation process and allows decision-makers to deliberate appropriately given an evaluation's findings.
Sponsor	The manufacturer, developer, distributor or agent of the technology being considered for evaluation.

Structural uncertainty	Uncertainty relating to the range of assumptions and judgements necessary in constructing a model. This can include design features of the model (for example, the assumed standard pathway of care) as well as judgements about the relevance of evidence, assumptions about appropriate distributions for parameters and alternative methods of estimation.
Synthesis of evidence	A generic term to describe methods used for summarising (comparing and contrasting) evidence into a clinically meaningful conclusion to answer a defined clinical question. This can include systematic review (with or without meta-analysis), and qualitative and narrative summaries.
Systematic review	Systematic reviews adopt a scientific approach to identify and consolidate all the available evidence pertaining to a specific research question and minimize bias. Systematic reviews are carried out according to a pre-defined protocol, which sets out the scope of the systematic review and details of the methodology to be employed throughout the review. Key components of a systematic review include: systematic and extensive searches to identify all the relevant published and unpublished literature; study selection according to pre-defined eligibility criteria; assessment of the risk of bias for included studies; presentation of the findings in an independent and impartial manner and a discussion of the limitations of the evidence and of the review
Technology assessment	The process of evaluating the clinical, economic and other evidence on the use of a technology to formulate guidance on its most efficient use.
Time horizon	The time horizon used for an economic evaluation depends on the nature of the disease under consideration and the purpose of the analysis. If a long-term time horizon is used, all costs that are expected to arise over this period must be included in the analysis. This may involve extrapolating current costs to the future, or applying different costs at various time points during the time period. Long-term time horizons are applicable for chronic conditions that are associated with ongoing medical management, rather than a cure. Acute conditions can be modelled with a shorter time horizon.
Tornado diagram	A method of presenting multiple univariate sensitivity analyses on one graph. Tornado diagrams allow the reviewer to assess which of the model's parameters have the greatest influence on the model's results.
Transitional probabilities	Applies only to Markov models and is the probability of moving from one state to another at the end of a cycle.
Treatment sequence	Used to describe when the intervention being evaluated and the comparator are used in succession in the management of a condition.
Uncertainty analysis	Investigates the sensitivity of analysis results to variation in assumptions and parameters.
Univariate/one way sensitivity analysis	It allows a reviewer to assess the impact that changes in a certain parameter will have on the model's results. This is the simplest form of sensitivity analysis since only one parameter is changed at one time.
Utility	A measure of the strength of a person's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.
Variable	A measurement that can vary within a study, (for example, the age of participants). Variability is present when differences can be seen between different people or within the same person over time, with respect to any characteristic or feature that can be assessed or measured.

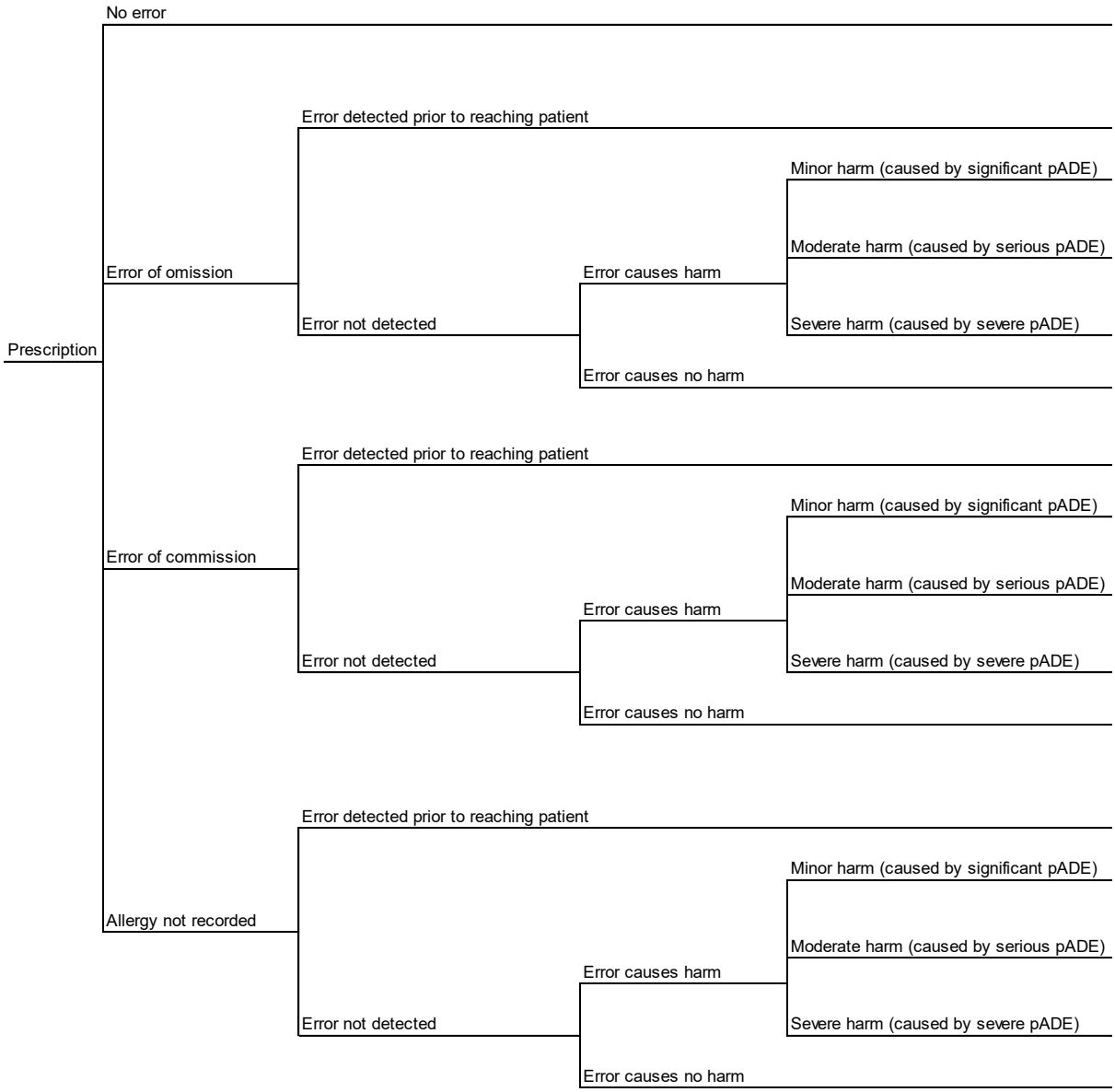
Appendix A: Examples of Patient Pathways for a Health Economic Model

Examples of patient pathways for a health economic model

This appendix provides 3 examples of patient pathways for a health economic model. All have been used by YHEC in projects available within the public domain.

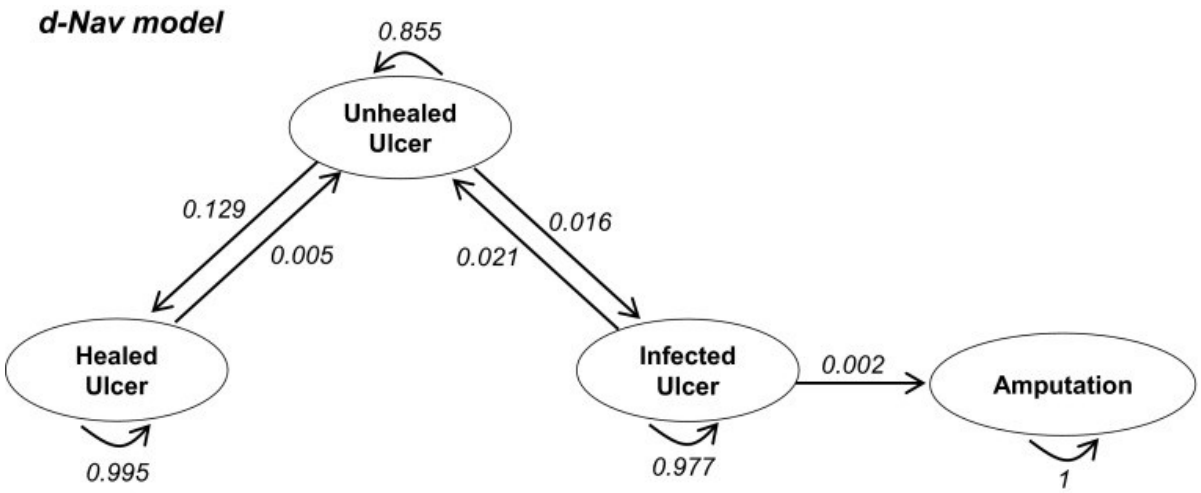
1. Medicine optimisation clinical guideline (NG5)

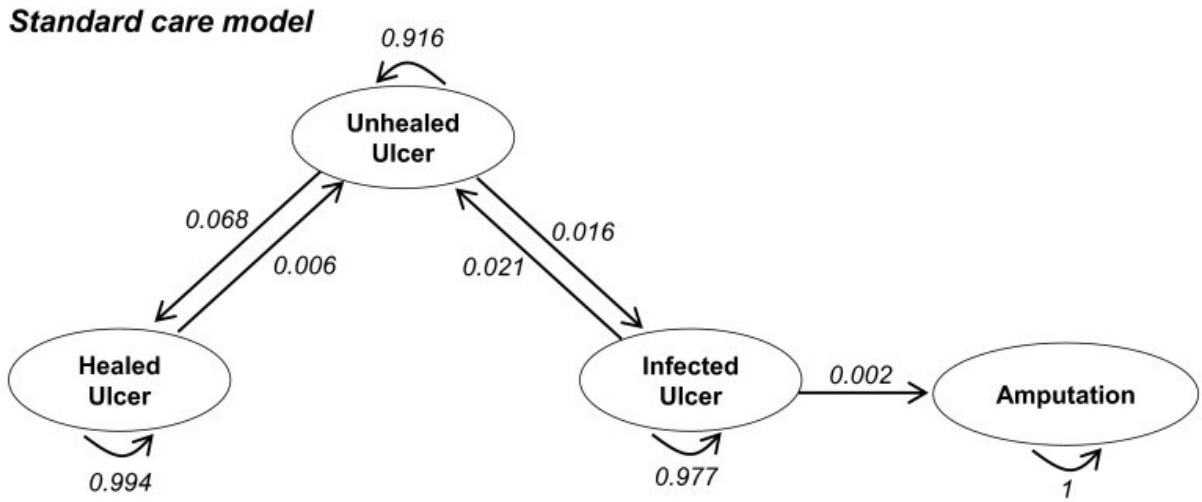
Model structure used for interventions (e.g. medication review) that attempt to reduce medication errors. Decision tree approach whereby each branch represents a mutually exclusive pathway that a patient may take. Full details of the model and what decisions it informed are available here.



2. A device for people with diabetes at high risk of neuropathic foot ulcers

A Markov model containing four health states (no ulcer, uninfected ulcer, infected ulcer, and amputation) was developed to compare the device with current NHS standard care. Specific costs and health outcomes were allocated to each health state. A full description of the model and how patients move between states (transition probabilities) is available here.





3. Decision tree and Markov model for the treatment of chronic sinusitis (MTG30 – XprESS)

This economic model consisted of a decision tree followed by a Markov model with 2 health states. Full details of the model and what decisions it informed are available here.