NICE National Institute for Health and Care Excellence

NICE International

Role of NICE in the UK – turning evidence into policy

Santiago : January 2016

Professor David Haslam
Chairman

Overview

- NICE…what is it?
- Core principles
- Cost effectiveness and decision making
- Technology Appraisals
- Clinical guidelines and ‘Quality Standards’
- Lessons from the ‘NICE Way’

Why NICE was set up

Established in 1999 as the:

National Institute for Clinical Excellence

- To reduce variation in the availability and quality of treatments and care (the so called ‘postcode lottery’)
- To resolve uncertainty about which medicines and treatments work best and which represent best value for money for the NHS
- To encourage uptake of good value innovations

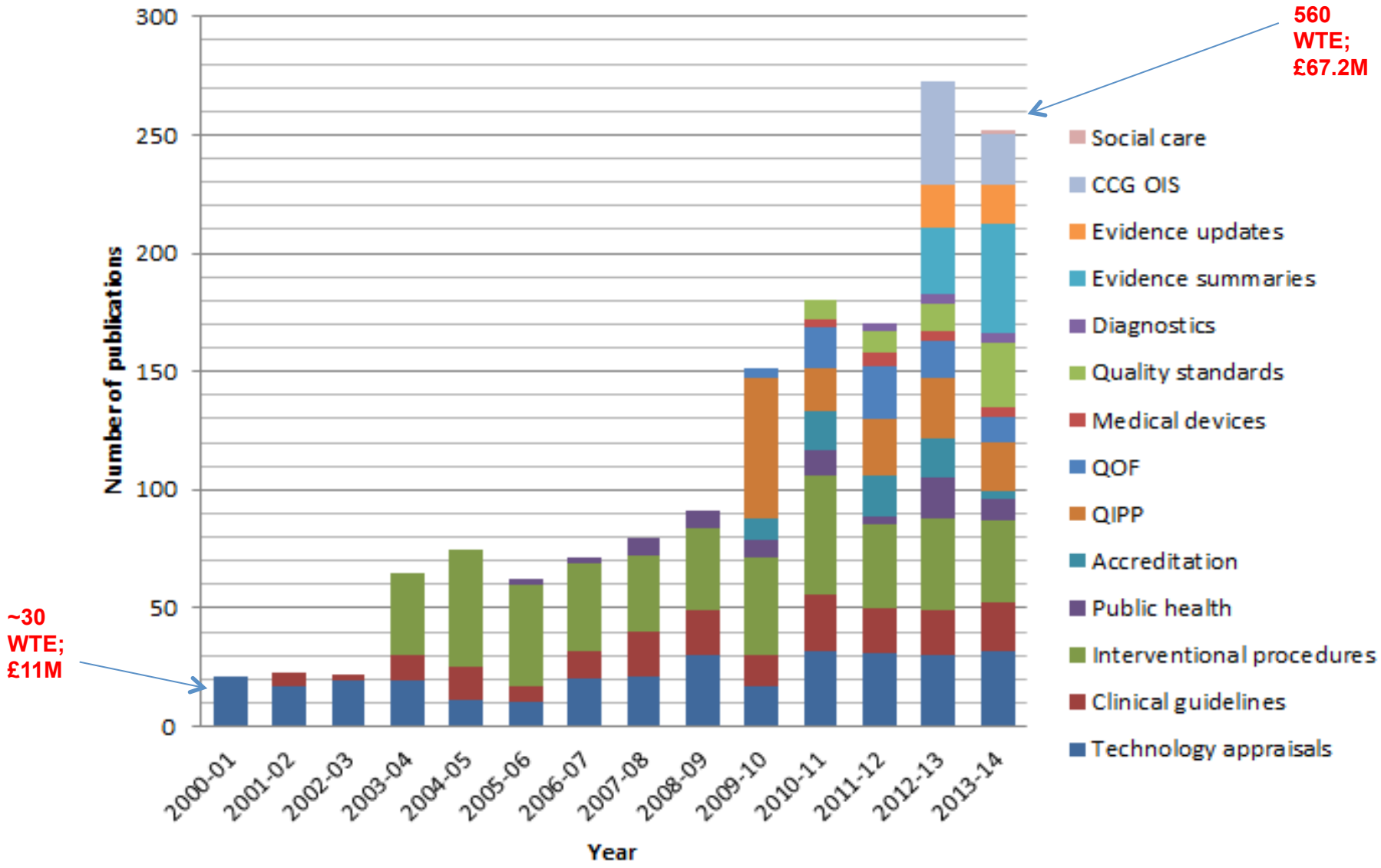
Establishing NICE: expectations

- National, authoritative source of advice
- Guidance based on effectiveness and cost effectiveness
- Inclusive and consultative approach
- Independent and efficient
- A service for the NHS and the public which uses it
- Broad support from professional and user groups

A Brief History

1999: Technology appraisals
Clinical guidelines
2002: Interventional procedures
Implementation
2005: Public health guidelines
2008 : NICE International
2009: Cost saving MedTec programme (new technologies)
Diagnostics
NHS Evidence
2011: National Prescribing Centre (now Medicines Prescribing Centre)
2013: Social care guidelines
Highly specialised technologies
2014: Safe staffing guidelines

NICE: changes and evolution



NICE: Improving outcomes for people

The NICE portfolio in 2014

Core principles of NICE's work

- Based on the best evidence available
- Expert input
- Patient and carer involvement
- Independent advisory committees
- Genuine consultation
- Regular review
- Open and transparent process
- Social values and equity considerations

Is NICE guidance mandatory?

YES NHS organisations are legally required to provide access to drugs we have approved through our technology appraisal programme.

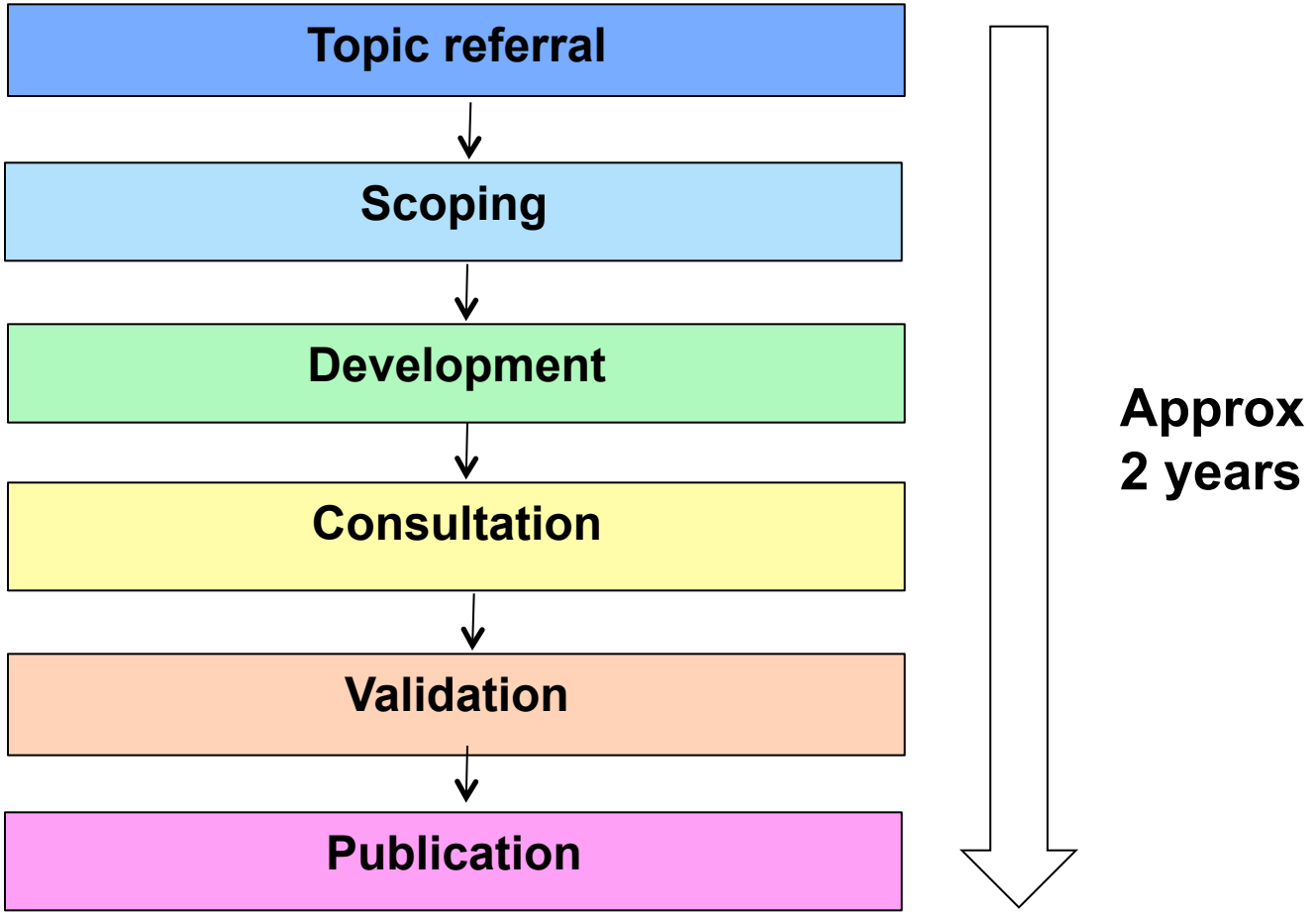
NO All other NICE guidance (clinical guidelines, public health, social care etc) is advisory, not mandatory. It is a summary of the evidence of what works, but it is not intended to replace clinical judgement.

NHS constitution 2012

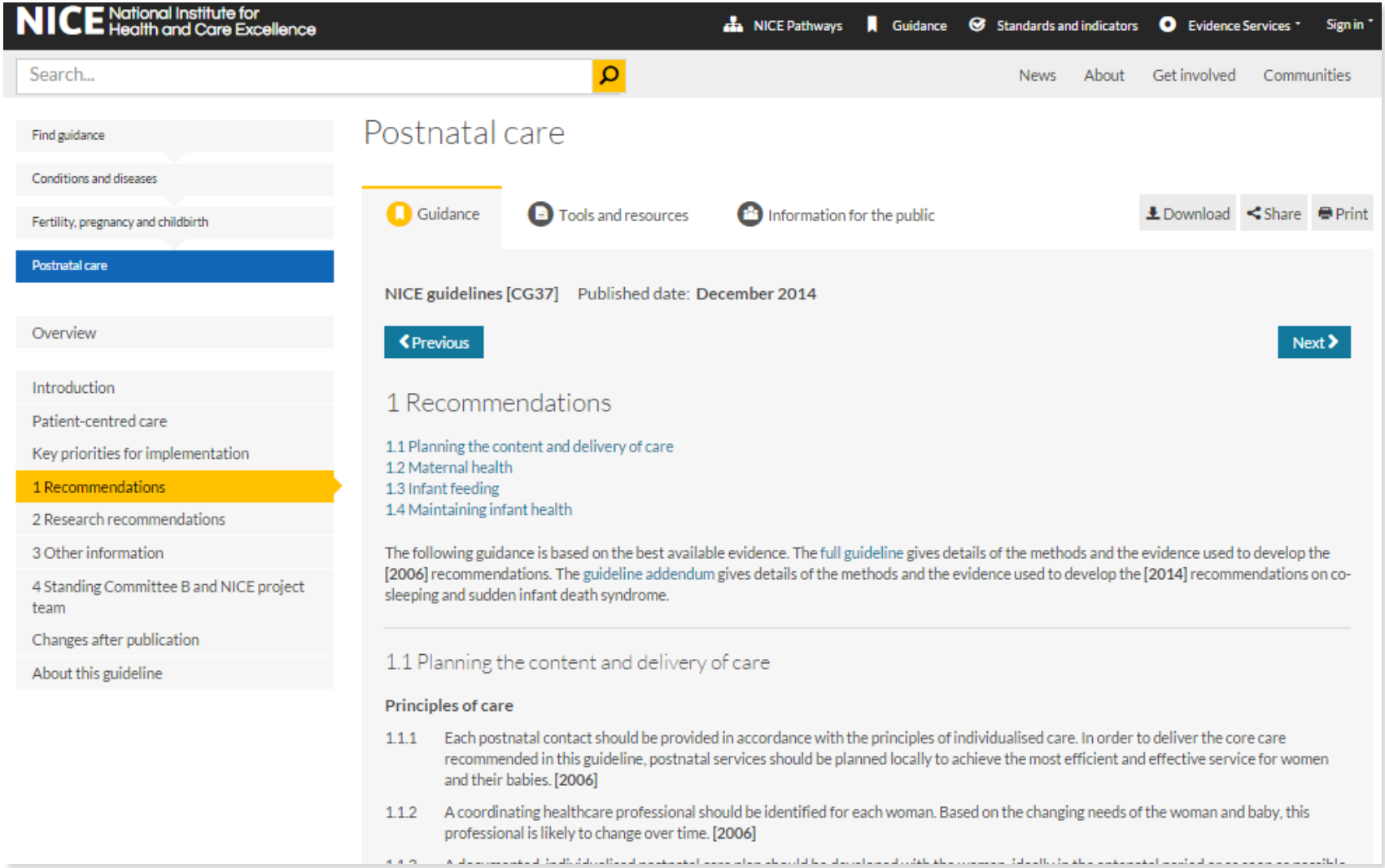
"You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you."

How does NICE develop recommendations?

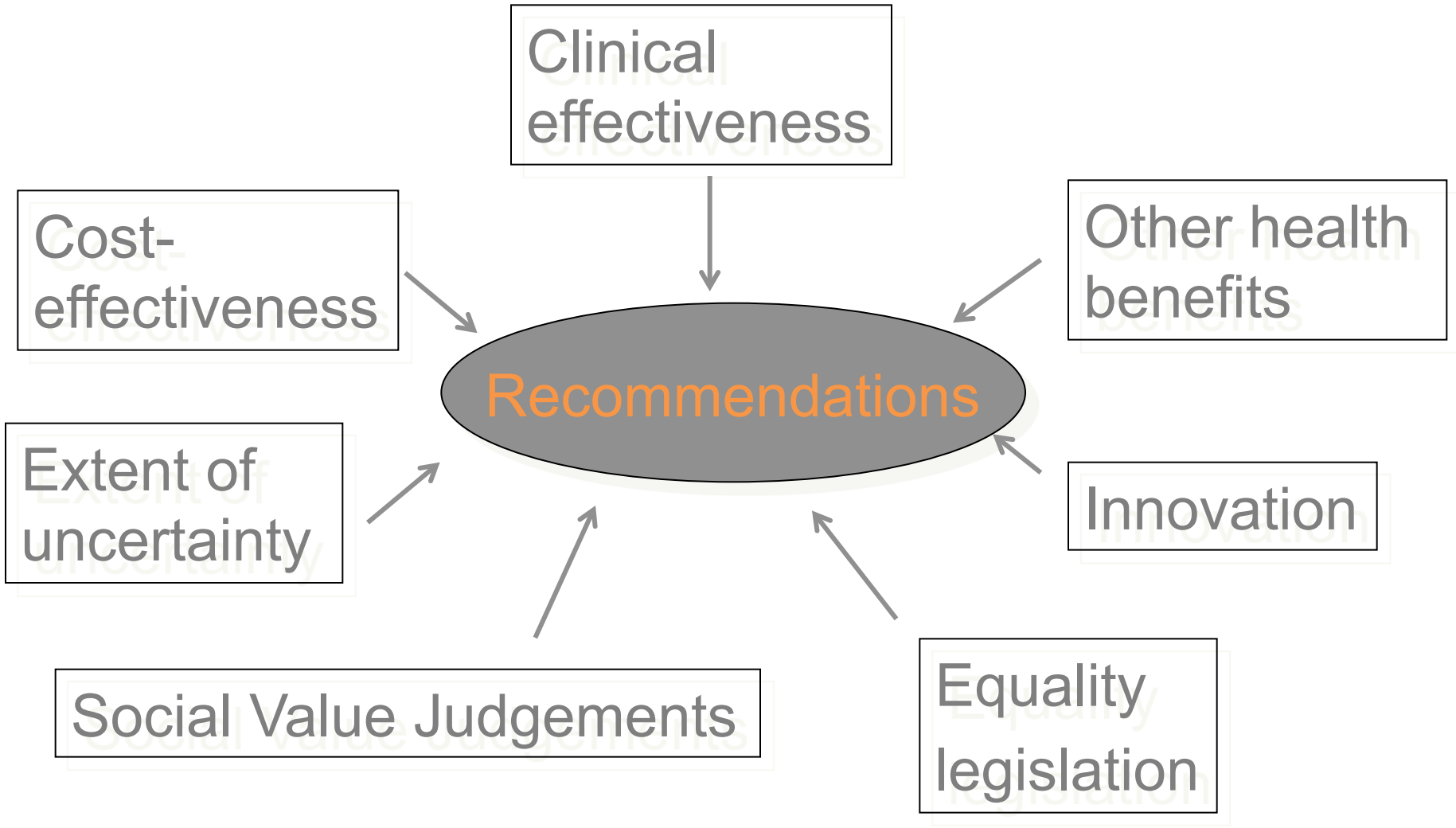
The stages of guidance development



The finished product



Committee decision making



Patients' and service users' views matter

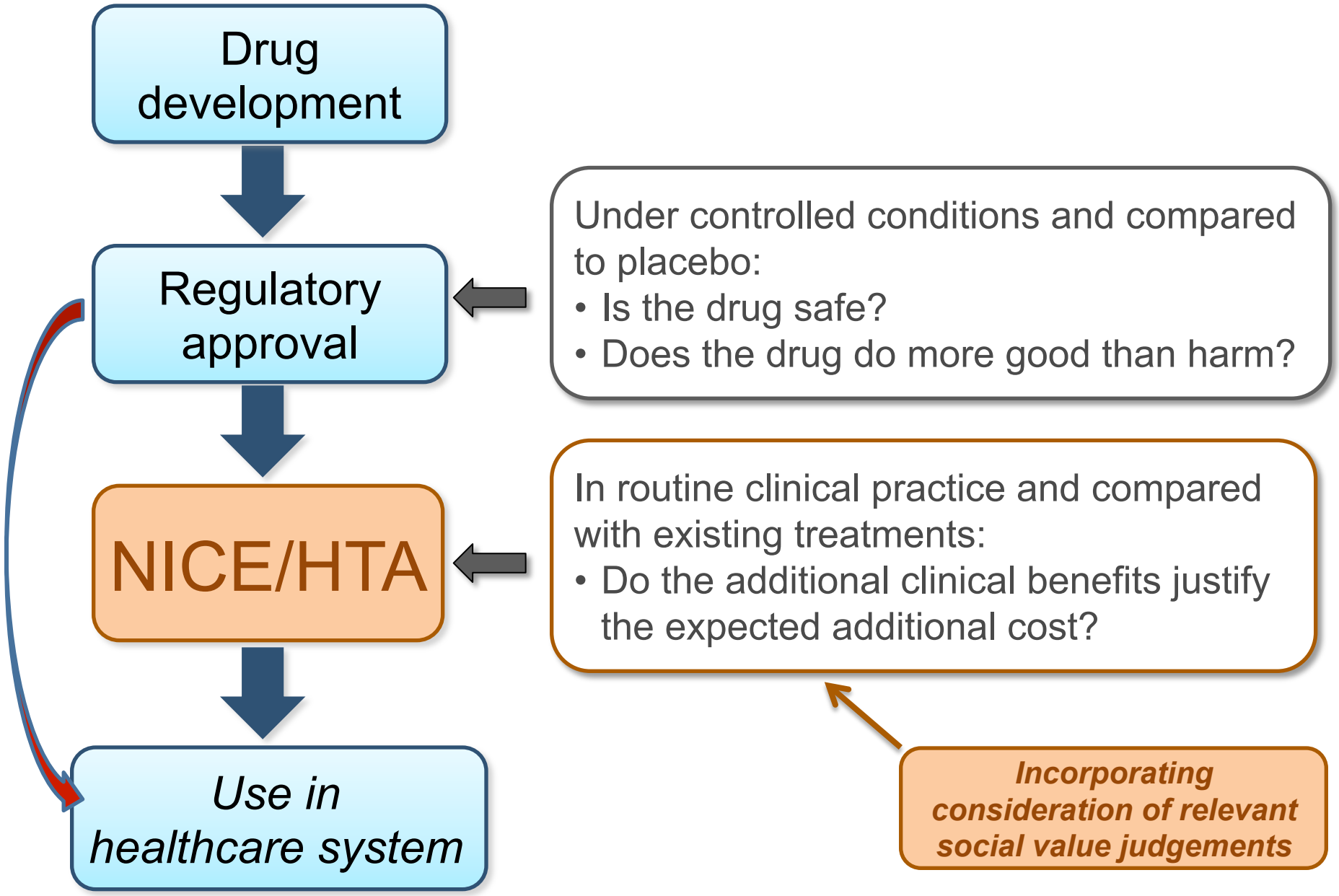
Patient preferences

Example: kidney dialysis

Committee assumed patients would prefer dialysis at home.

Some patients told us they disliked home machines as it meant their illness dominated their lives.

Technology Appraisals (HTA)


Drug development
Regulatory approval
NICE/HTA
Use in healthcare system
Under controlled conditions and compared to placebo:
• Is the drug safe?
• Does the drug do more good than harm?
In routine clinical practice and compared with existing treatments:
• Do the additional clinical benefits justify the expected additional cost?
Incorporating consideration of relevant social value judgements

Economic evaluation of new drugs/treatments

- How well does the drug/treatment work in relation to how much it costs compared to standard practice in the NHS ?
- Recognises the reality of fixed NHS resources
- Exposes the opportunity cost of new interventions, that is if you spend money on a new healthcare intervention, you have to take away the health care from someone else
- Enables consistency and fairness across all decisions

Cost effectiveness

Clinical effectiveness

NICE Technology appraisals

Guidance on the use of new and existing medicines, treatments and procedures within the NHS

Two types of appraisals:

Multiple Technology Appraisal (MTA)
Single Technology Appraisal (STA)

- Independent academic groups carry out systematic review and develop economic model (**MTA**) [60 weeks]
- Critique the evidence submitted by manufacturer (**STA**) [30-43 weeks]
- 4 Standing Committees
  - Independent
  - Multi-disciplinary – includes industry
- Opportunity for key stakeholders to appeal against final draft guidance

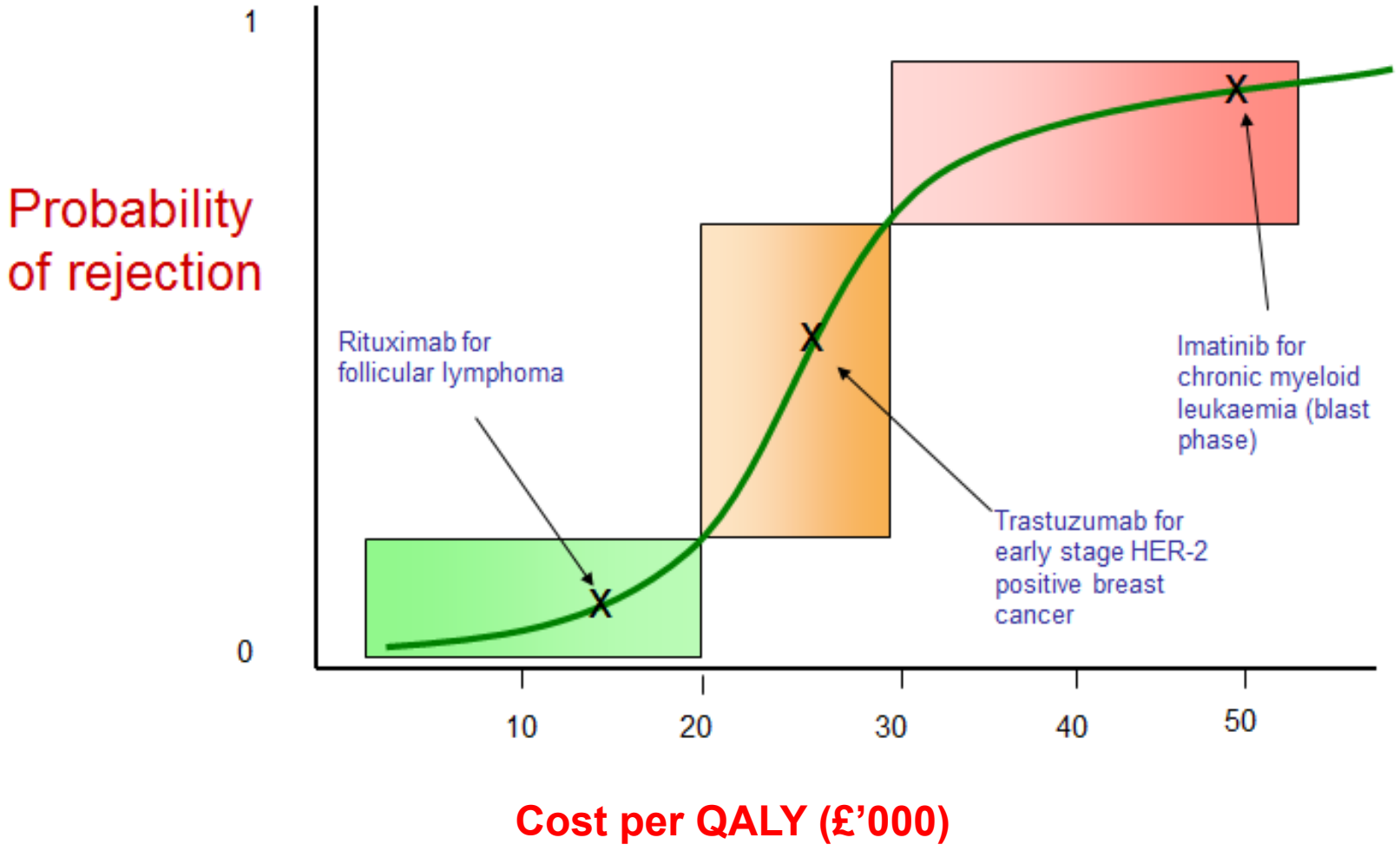
Recommendations to be implemented within 3 months

Cost effectiveness – *Incremental cost-effectiveness ratio (ICER):*

$$\frac{\text{cost}_{new} - \text{cost}_{current}}{\text{health gain}_{new} - \text{health gain}_{current}}$$

At NICE, health gain is expressed as quality adjusted life years (QALYs) which allows us to calculate the **cost per QALY** for any technology under consideration

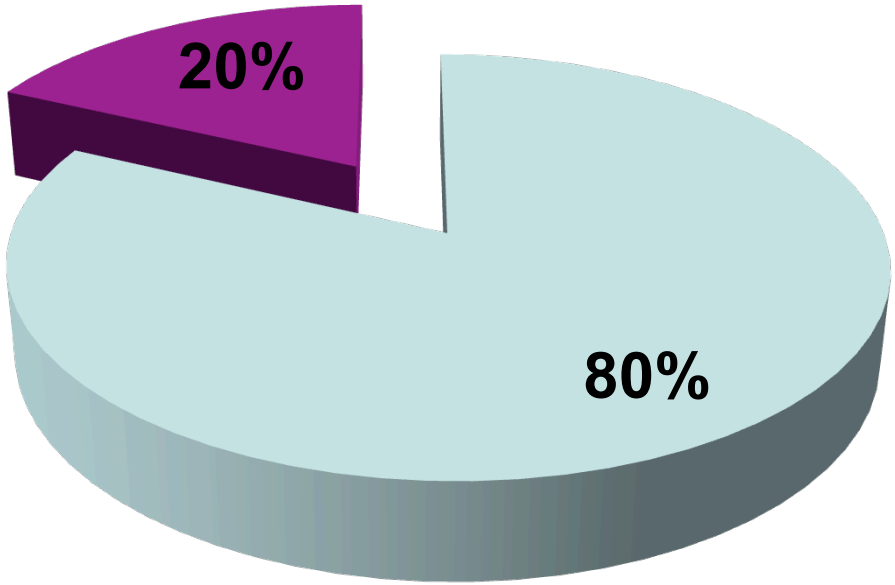
Establishing value: cost effectiveness



Breakdown of recommendations

328 drug appraisals published from 1 Mar 2000 – 31 December 2014
Containing 564 individual recommendations

‘no’ or
‘only in research’



‘Yes’ recommended for routine use
or under specific circumstances

Application of 'special circumstances'

Table 1

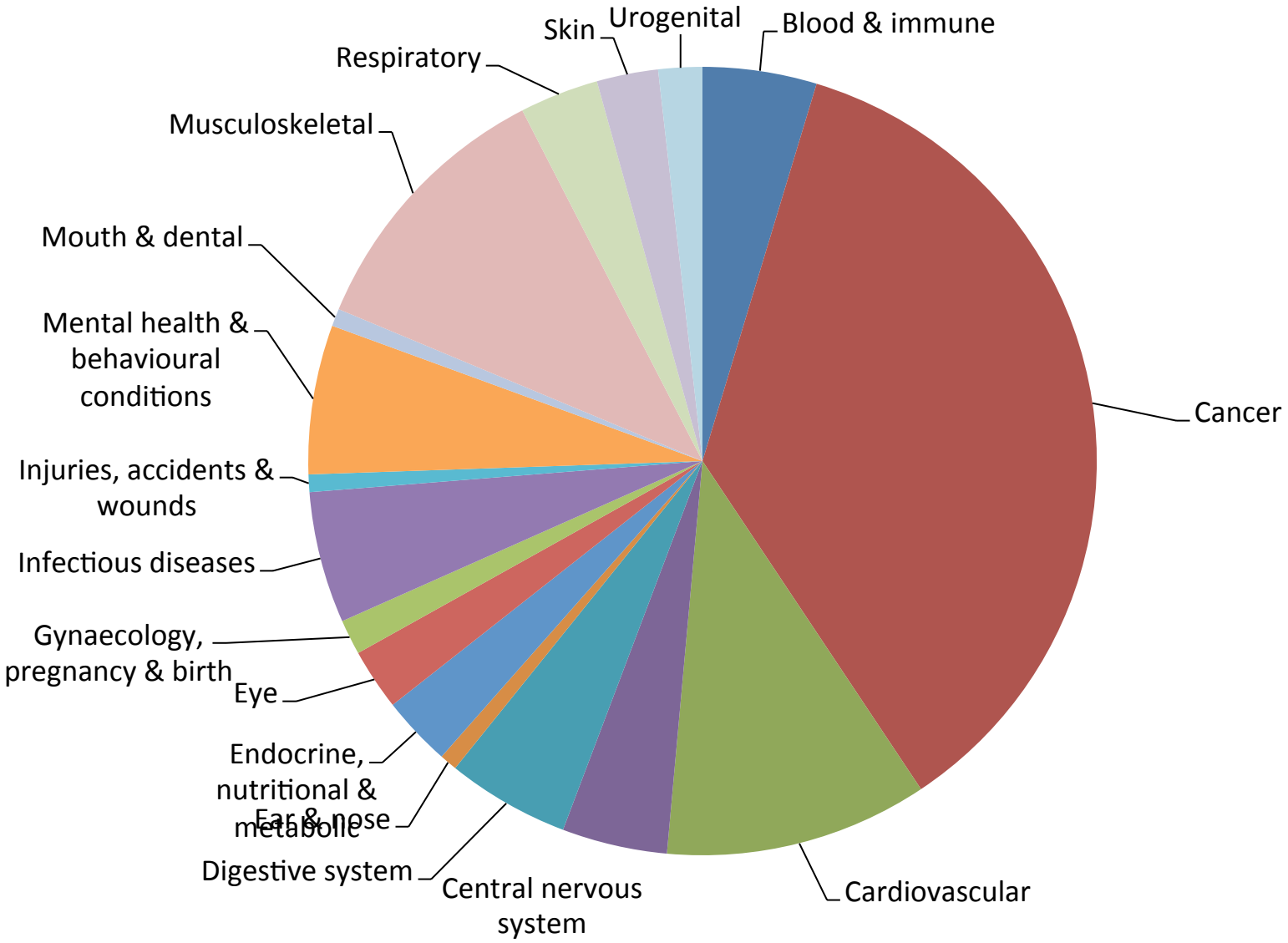
Application of 'special circumstances' in the appraisal of some products with incremental cost-effectiveness above £30 000 per quality adjusted life year

Topic	ICER ('000s)	Severity	End of life*	Stakeholder persuasion	Significant innovation	Disadvantaged population	Children
Riluzole (motor neurone disease)	38–42	✓	✓	✓			
Trastuzumab (advanced breast cancer)	37.5	✓			✓		
Imatinib (chronic myeloid leukaemia)	36–65	✓			✓		
Imatinib (gastrointestinal stromal tumour)		✓	✓		✓		
Pemetrexed (malignant mesothelioma)	34.5	✓	✓			✓	
Ranizumab (age-related macular degeneration)	>>30			✓	✓		
Omalizumab (severe asthma)	>30	✓		✓	✓		
Sunitinib (advanced renal cancer)	50	✓	✓	✓	✓		
Lenalidomide (multiple myeloma)	43	✓	✓		✓		
Somatotropin (growth hormone deficiency)	n/a			✓	✓		✓
Chronic subcutaneous insulin infusion (childhood Type 1 diabetes)	n/a			✓			✓

*End-of-life considerations have only been explicitly taken into account since January 2009 on the basis of supplementary advice from the Institute to the Appraisals Committee.
ICER, incremental cost-effectiveness ratio (£ per quality-adjusted life year).

Rawlins, Barnett, Stevens Br J Clin Pharmacol 2010

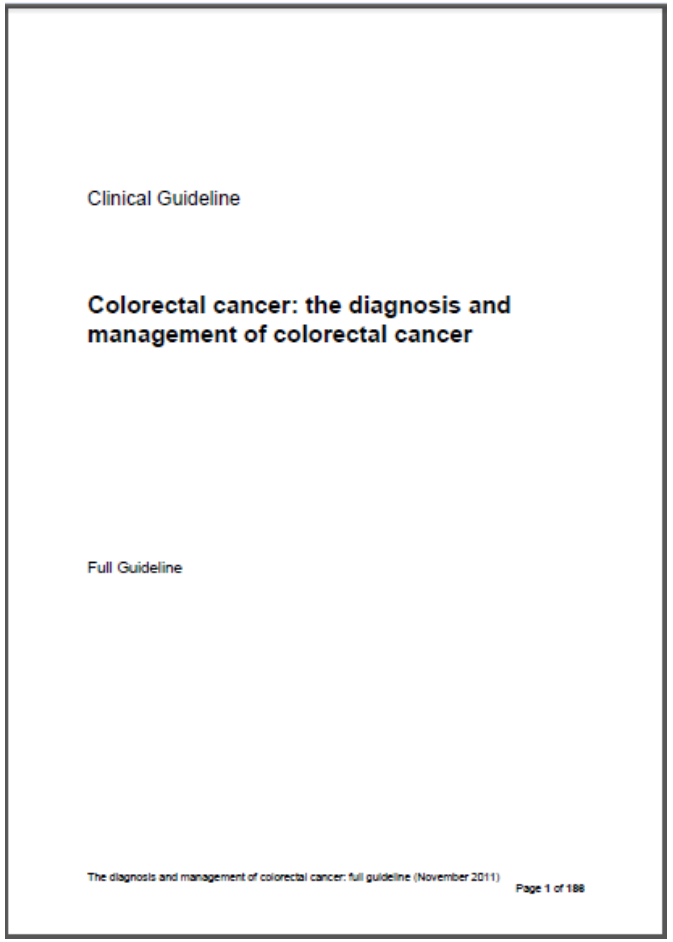
Therapeutic areas in technology appraisal topics



Looking beyond the assessment of individual “technologies” – clinical guidelines, pathways and quality

Clinical guidelines - what are they?

- Broad guidance covering all or specific aspects of the management of a particular condition (the pathway) [up to 24 months]
- Incorporates technology appraisals, interventional procedures and other related NICE guidance where appropriate
- Recommendations advisory only (but can be used to develop *quality standards* to assess clinical practice and inform payment)


Clinical Guideline

Colorectal cancer: the diagnosis and management of colorectal cancer

Full Guideline

The diagnosis and management of colorectal cancer: full guideline (November 2011)

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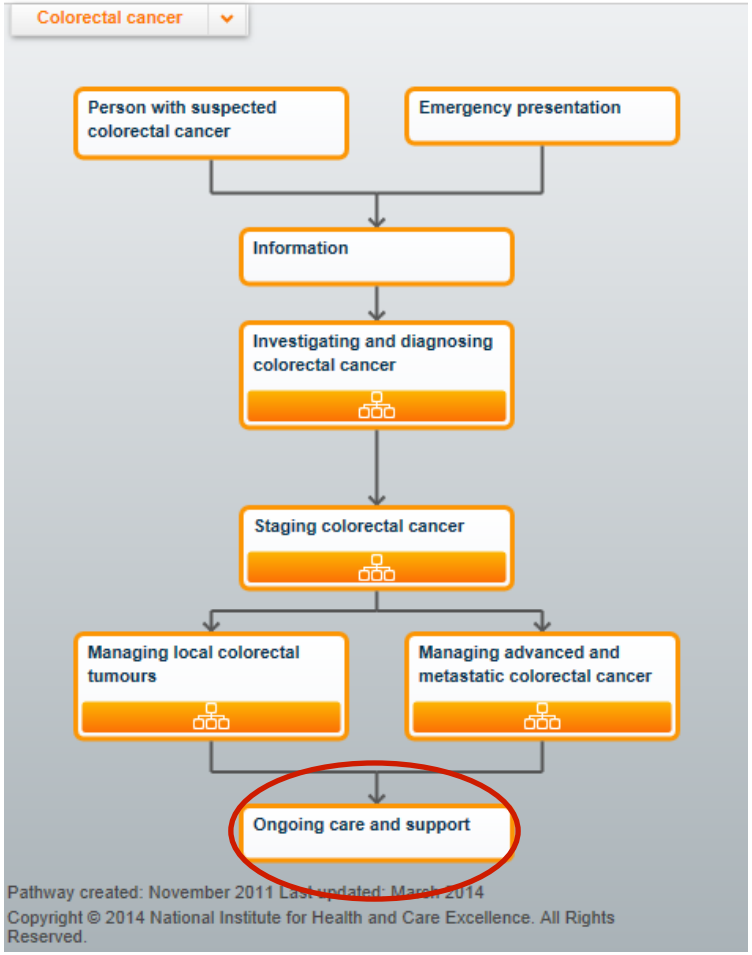
Guidelines.
Not tramlines..

NICE Pathways

Colorectal cancer overview



Ongoing care and support

Offer follow-up to all patients with primary colorectal cancer undergoing treatment with curative intent. Start follow-up at a clinic visit 4–6 weeks after potentially curative treatment.

Offer patients regular surveillance with:

- a minimum of two CTs of the chest, abdomen, and pelvis in the first 3 years **and**
- regular serum carcinoembryonic antigen tests (at least every 6 months in the first 3 years).

Offer a surveillance colonoscopy at 1 year after initial treatment. If this investigation is normal consider further colonoscopic follow-up after 5 years, and thereafter as determined by cancer networks. The timing of surveillance for patients with subsequent adenomas should be determined by the risk status of the adenoma.

NICE has produced a pathway on colonoscopic surveillance for people with inflammatory bowel disease or adenomas.

Start reinvestigation if there is any clinical, radiological or biochemical suspicion of recurrent disease (see investigating and diagnosing colorectal cancer).

Stop regular follow-up:

- when the patient and the healthcare professional have discussed and agreed that the likely benefits no longer outweigh the risks of further tests **or**
- when the patient cannot tolerate further treatments.

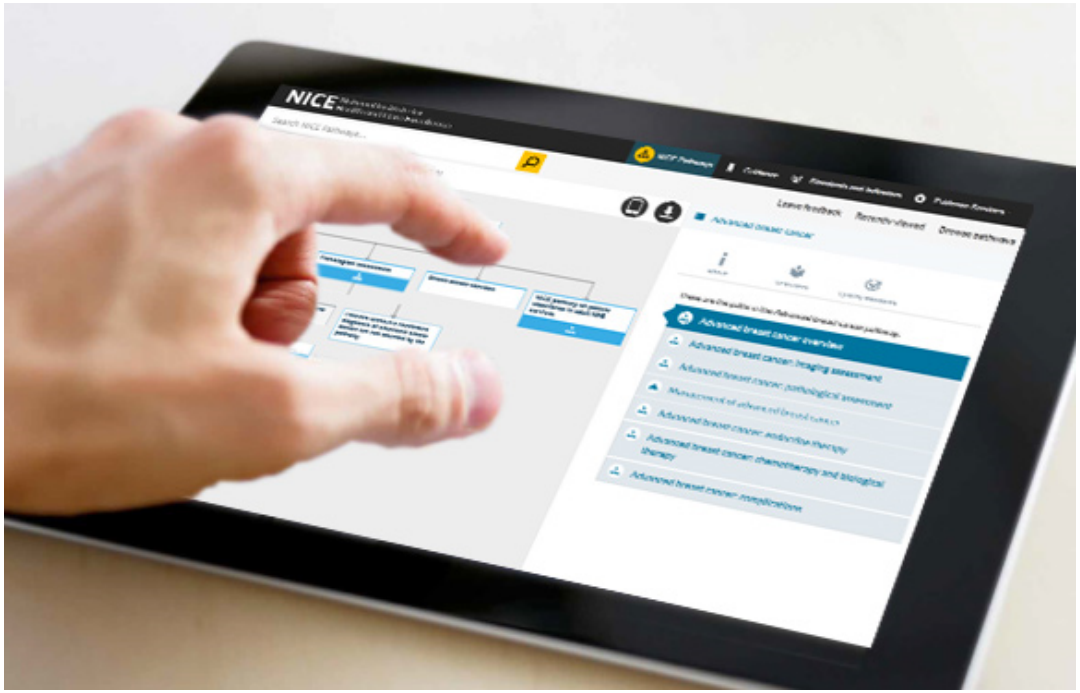
NICE has produced cancer service guidance on supportive and palliative care

Quality standards ›

Source guidance ›

NICE Pathways- guidance at your fingertips

Pathways brings together all NICE guidance, quality standards and support in easy-to-navigate flowcharts

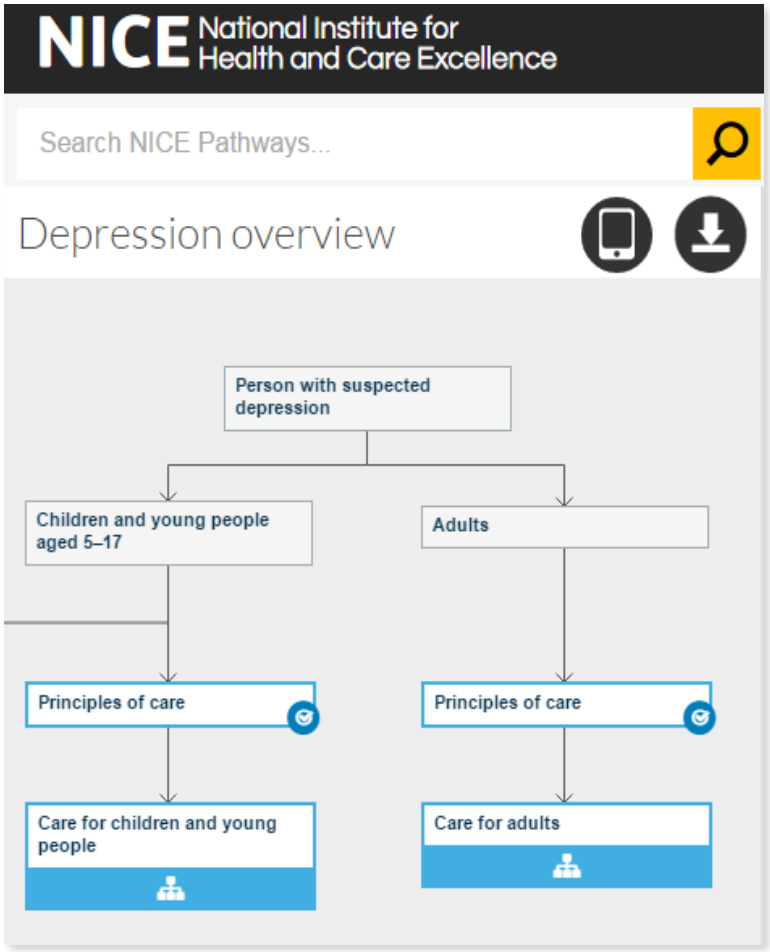


A different way of seeing everything NICE has said about a topic or condition that interests you

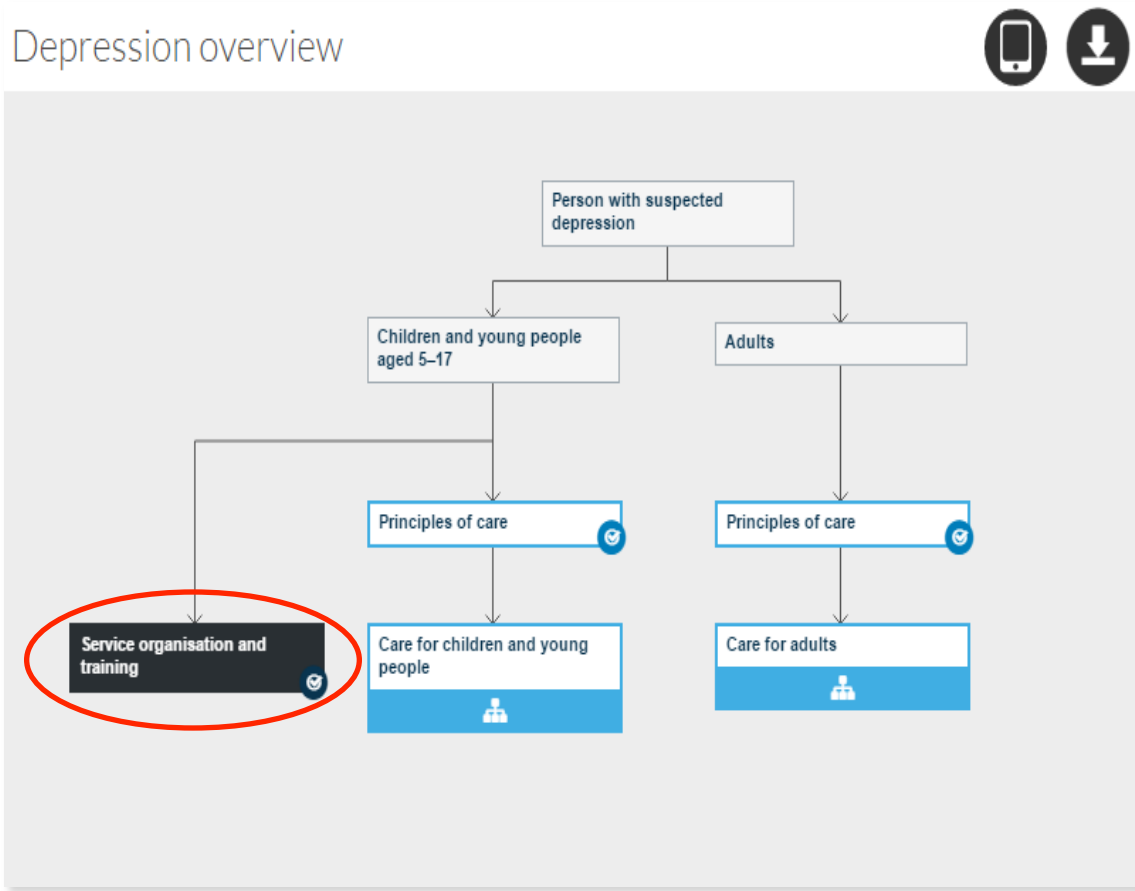
Example: depression pathway

1. Brings together related NICE guidance, between and within topics
2. A visual and interactive format that provides a way to quickly view and navigate guidance
3. Provides a useful, more intuitive way of viewing guidance
4. Links other products – Quality Standards, implementation support tools etc

Easier, quicker access to the evidence



Detailed advice appears on the right



Depression

Service organisation and training

Organisation and planning of services

CAMHS and PCT s should:

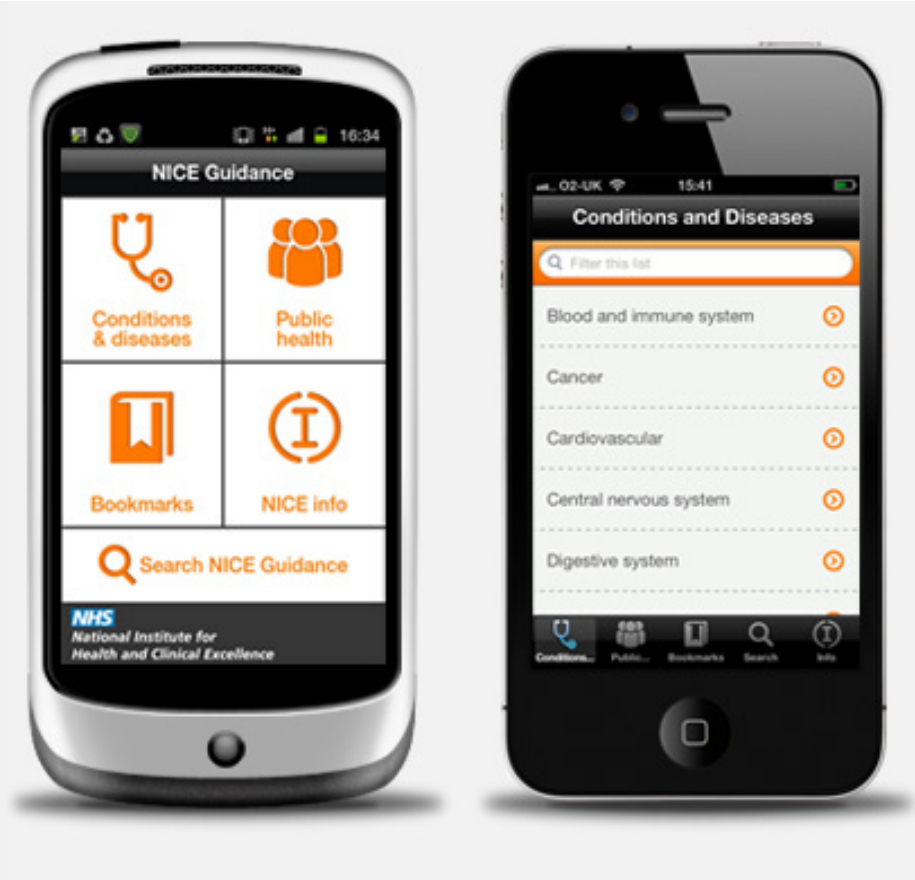
- consider introducing a primary mental health worker (or CAMHS link worker) into each secondary school and secondary pupil referral unit as part of tier 2 provision within the locality
- routinely monitor detection, referral and treatment rates of children/young people with mental health problems from all ethnic groups in local schools and primary care
- use information about these rates to plan services, and make it available for local, regional and national comparison.

Primary mental health workers (or CAMHS link workers) should:

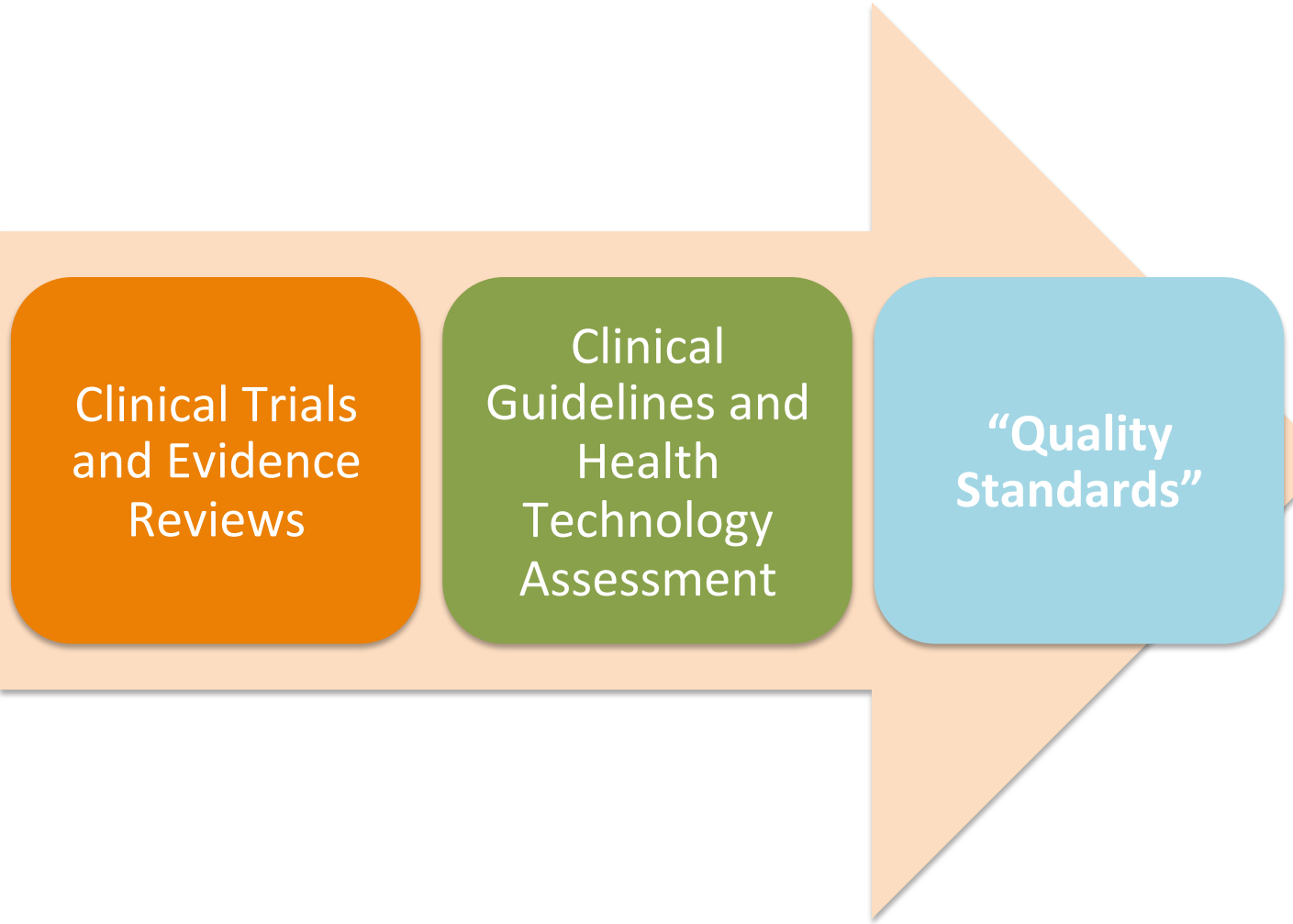
- establish clear lines of communication between CAMHS and tier 1 and tier 2, with named contact people in each tier/service

NICE guidance app for iPhone and Android smartphone

- Search over 750 pieces of NICE guidance.
- Download it today free from Apple's iStore and the Android Market.
- Bookmark key recommendations
- Email them to a colleague



From evidence to setting standards and improving quality



- Medical education and professional training
- Performance management
- Budget management
- Provider payment mechanisms incl. case-based payment
- Communication of entitlement to patients and their families
- Clinical audit and provider benchmarking
- Provider regulation and accreditation

What are quality standards?

Quality standards are a concise set of evidence-informed statements, designed to drive and measure priority quality improvements, within a particular area of care (e.g. acute management of stroke).

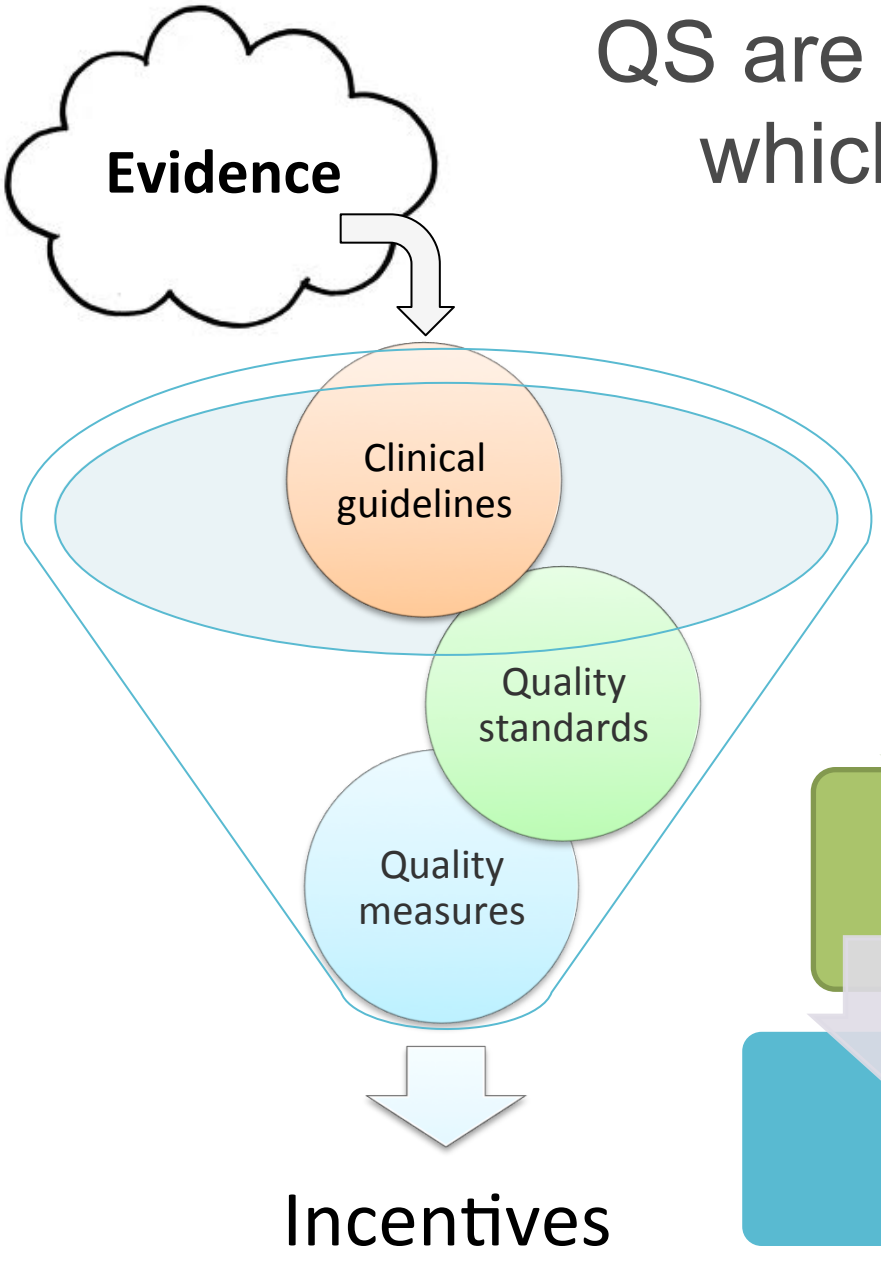
Quality Standards aim to improve quality and reduce variation

1. **Markers of high quality care** (*not* minimum standards!) in terms of: *clinical effectiveness, safety,* and *patient experience*
2. Focus on areas **where sub-optimal clinical practice is common**
3. Derived from **best available evidence**, e.g. WHO, NICE, other local guidance
4. **Aligned with government/payer priorities**
5. **Produced collaboratively** with stakeholders (policymakers, payers, hospital managers, clinicians, service users, professional/patient organisations).

Quality Standards do *not*:

- Review or re-assess the underlying evidence base
- List *all* necessary components of acceptable care

QS are an evolutionary process which drives improvement



The starting point is the evidence base (clinical trials etc.)

Evidence is distilled to produce clinical guidelines

Quality standards are derived from evidence-based clinical guidelines

QS indicators and measures can inform quality initiatives and financial incentives.

Example: Colorectal Cancer Quality Standard (QS20)

- **Quality statement 1**

People with suspected colorectal cancer without major comorbidity are offered diagnostic colonoscopy

Quality measure

Structure: Evidence of local arrangements to ensure people with suspected colorectal cancer without major comorbidity are offered diagnostic colonoscopy.

Process: Proportion of people with suspected colorectal cancer without major comorbidity who receive diagnostic colonoscopy.

Numerator – the number of people in the denominator who receive diagnostic colonoscopy.

Denominator – the number of people with suspected colorectal cancer without major comorbidity.

Lessons from the ‘NICE way’

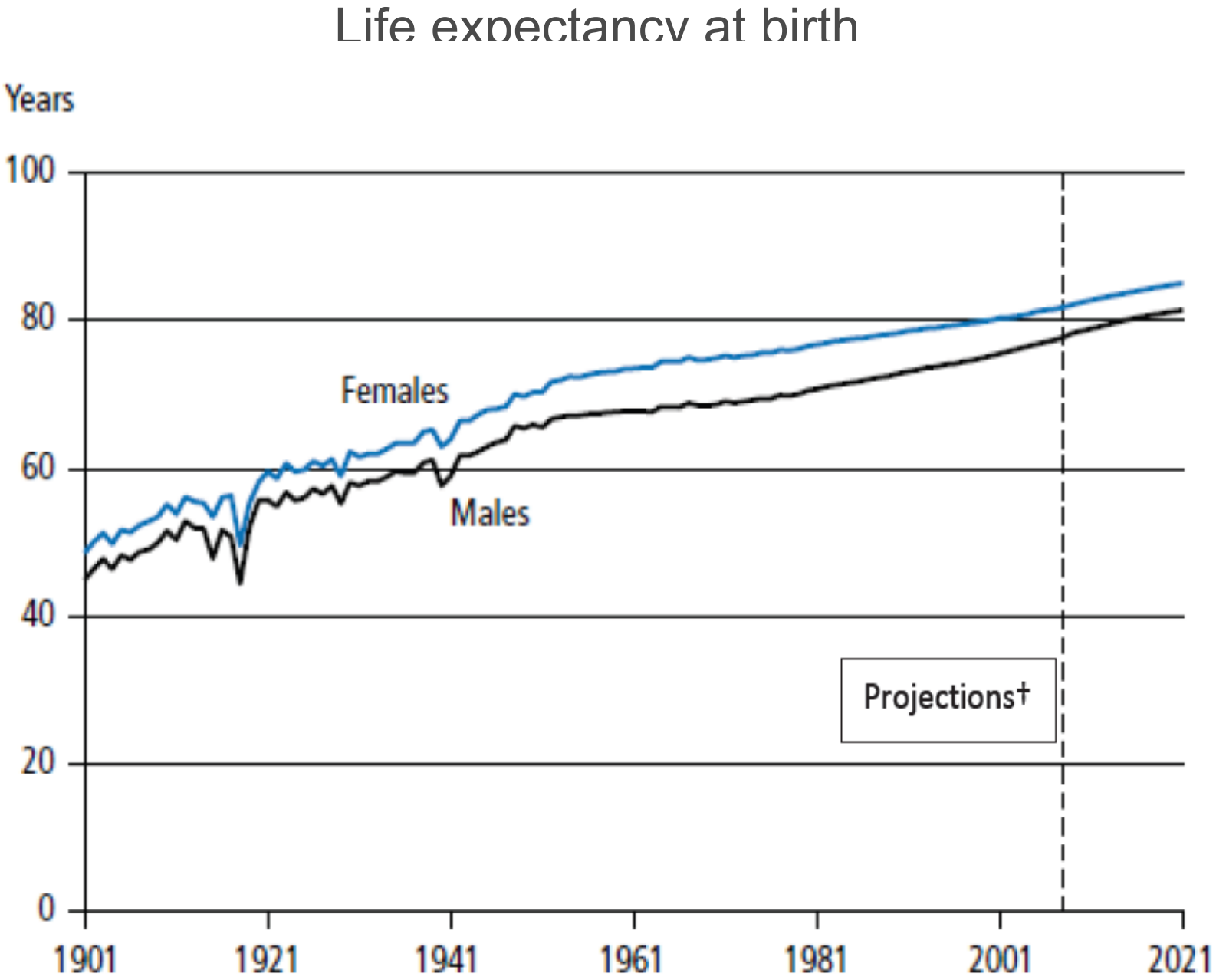
Good governance structures can significantly increase the legitimacy (in the eyes of the law and of the public) of priority setting decisions, but:

- The process needs a degree of flexibility to avoid being too rigid
- The system needs to be responsive and be able to adapt to changing needs
- Importance of reviewing processes/methods
- Importance of engaging professionas

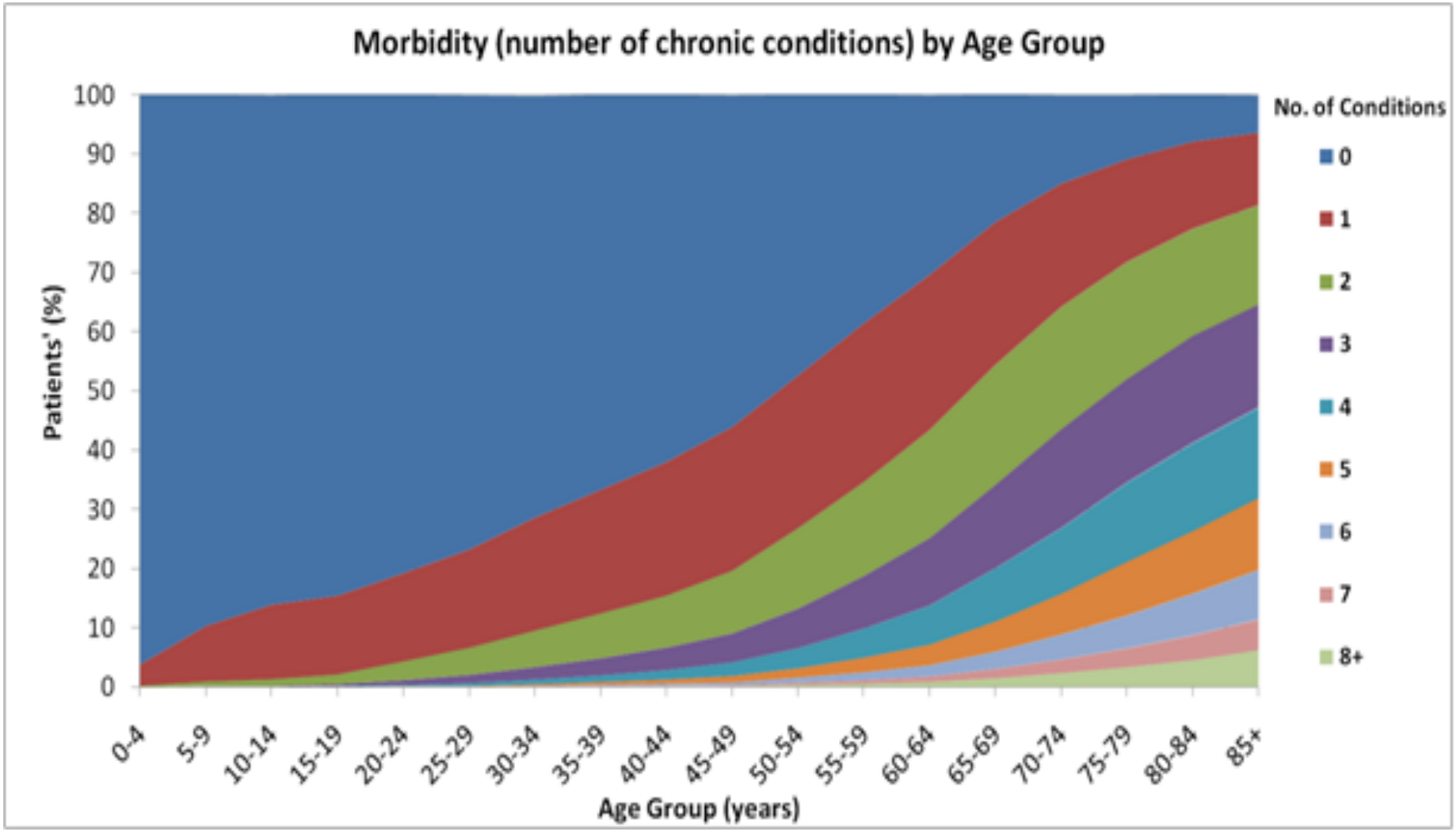
An inclusive, multidisciplinary approach can improve both the quality and legitimacy of decisions made

What’s new and in the pipeline?

Ageing…a medical success story



Multimorbidity is common in Scotland



– The majority of over-65s have 2 or more conditions, and the majority of over-75s have 3 or more conditions

NICE and social care

- Now working on guidelines and quality standards for social care
- A more integrated approach to supporting people, crossing health, public health and adults and children's services
- Developed in partnership with service users, carers and social care professionals

Thank you.

David.haslam@nice.org.uk