How NICE develops guidelines

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NGC National Guideline Centre

Who/What is NICE?

- National Institute for Health and Care Excellence
- Special Health Authority
  - established 1999
  - covering England and Wales (NI)
- Currently 'arms length body' and legally covers England only
- Public health guidance, clinical and social care guidance, technology assessment (new drugs), quality standards……

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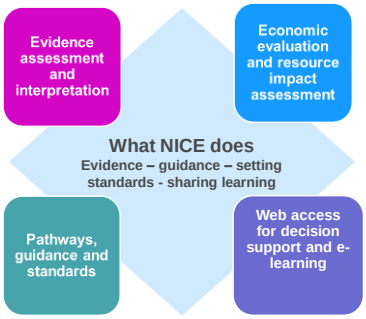

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NICE principles

- Evidence based
- Cost-effectiveness analysis
- Stakeholder involvement
- Patient/carer involvement
- Clear processes and transparency
- Social values
- Equalities

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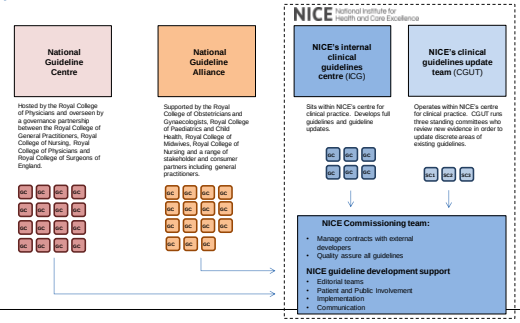
NICE's guideline development communities



National Guideline Centre

- Partnership of RCP / RCN / RCGP / RCS
- Hosted by the Royal College of Physicians since 2009
- (National Clinical Guideline Centre)
- Commissioned and funded by NICE to produce guidance
- Other commissions e.g. CCGs, charities

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National Guideline Centre

- Manage the development of guidelines according to NICE processes
- ~20 guidelines including
  - new guidelines
  - updates
- Provides technical expertise and support to the guideline committee

Technical support

- Technical team of health service researchers:
  - Guideline lead
  - Project manager/ Editorial assistants
  - Information scientist
  - Systematic reviewers
  - Health economist.

Clinical Guideline Development

What is a guideline?

- Series of statements to provide advice to healthcare professionals and services
- Health and Social care act- need to take account of quality standards
- Regulatory bodies such as CQC use as benchmark
- Courts use as benchmark

What a guideline will include…and won't

- Not a text book
- Not a substitute for clinical judgement
- Not cover all aspects of a clinical condition - built around series of 'key questions'
- Not include professional advice e.g. about good communication
- Generally not include how to deliver a service but what service should consist of

Guideline products

- The full guideline
- The short guideline
- NICE Pathway
- Information for the Public (IFP)

Main steps……

- NHS decide on topics
- NICE- processes, quality assurance
- Developer technical team – expertise in project management, information science, reviewing literature, health economics
- Guideline committee – Chair and multidisciplinary committee including patients/carers

Criteria for selection of topics

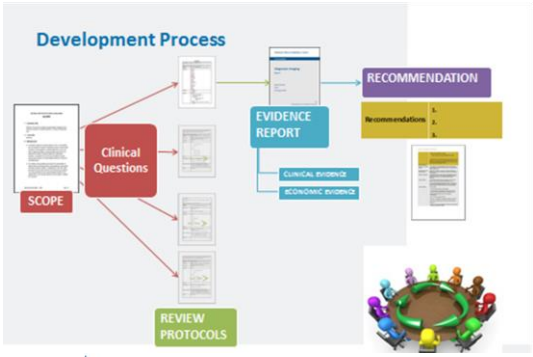
- Clinical guidelines commissioned by NHS England
- New guidelines from:
  -The quality standard library
  - Previous referrals where development has not yet commenced
- An existing guideline topic that has been identified as needing a significant update by NICE's Guidance Executive
- New topics

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/selecting-and-prioritising-guideline-and-quality-standard-topics

Criteria for selection of topics

- Burden of disability/disease
- Variation in practice
- Cost to NHS
- Existence of evidence base
- Will this guideline add value?
- Inform quality standards

One guideline ~ £400,000 to develop



Key stages of guideline development

Up to 12 weeks	GL/update commissioned	• Committee chair recruited
16 weeks	Scoping	• Scope Workshop held. • Consultation on scope. • Committee recruited.
Approx. 70 weeks	Development	• Guideline produced
18 weeks	Consultation	• Quality assurance by NICE • Public consultation (6 weeks) • Respond to feedback.
8 weeks	Validation	• Final quality assurance by NICE • Signoff by NICE's Guidance Executive
2-4 weeks	Publication	• Guideline prepared for publication • Embargoed release

What is a scope?

- Defines the key areas that the guideline will focus on
- Defines the population to be covered
- Identifies the health care settings that will be covered
- Sets out in detail the aspects of for example diagnosis, assessment, including investigations, and clinical management that will be reviewed
- Defines the areas that are excluded
- Process designed to ensure scope must be manageable in size and areas for inclusion must be prioritised

Process of Guideline Development

- Internationally agreed process
- Development of 'Key Clinical Questions'
- Write a protocol to search for evidence (**P**opulation, **I**ntervention, **C**omparison, **O**utcomes)
- Clear definition of each
- Search for evidence
- Review evidence
- Make recommendations based on evidence

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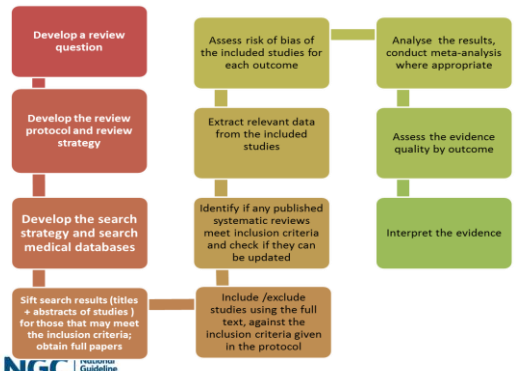
Protocol

Question	Population	Intervention	Comparison	Outcomes
Q14) What is the clinical/cost effectiveness of specialised pain interventions in patients with stable angina?	Adults with diagnosed stable angina - including people with diabetes, South Asians, refractory angina, minimal coronary heart disease and women, patients who have recurrence of anginal symptoms following revascularisation	TENS Spinal cord stimulation Cognitive Behavioural Therapy, Temporary or destructive sympathectomy. Analgesics (inc opioids – oral, transdermal, epidural, transthecal.), Myocardial laser (percutaneous or transmyocardial) EECP (Enhanced external counterpulsation) Acupuncture	Treatment vs. no treatment Treatment vs. placebo Treatment A vs. treatment B	All cause mortality, cardiac mortality, cardiovascular mortality, @ 5yr, 10yr Frequency of angina, improvement in exercise tolerance (immediate relief, symptoms over longer period e.g. 5yr, 10yr) Procedural morbidity e.g. @ 1m, 1yr Hospitalisation e.g. 5yr, 10yr Revascularisation rates e.g. 5yr, 10yr Quality of Life e.g. EQ-5D, SF-36, HAD, etc @ 1yr? 5yr, 10yr Adverse events



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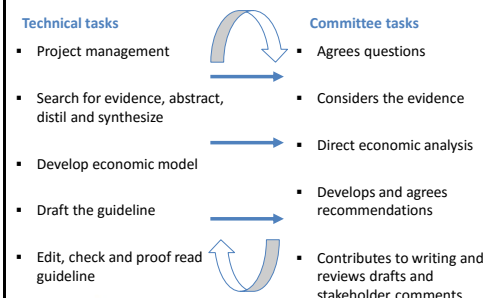

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Different types of questions and studies

- Diagnostic
- Prognostic
- Treatment/intervention
- Information and experience

Each need different types of study

Internationally agreed ways of grading evidence

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GRADE

Grading of Recommendations: Assessment, Development and Evaluation.

BY OUTCOME

Quality assessment							Proportion of patients with event OR mean difference (sd)		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsist-ency	Indirect-ness	Imprecision	Other consider-ations	Foam Sclero-therapy	Surgery	Relative (95% CI)	Absolute		CRITICAL
GSV reflux (6 weeks follow up)												
16	Randomised trial	serious[a]	serious[b]	None	Very serious[c]	none	276/786 (35.1%)	217/792 (27.4%)	RR 1.26 (1.09 to 1.45)	71 more per 1000 (from 25 more to 123 more)	VERY LOW	HIGH
Adverse events – thrombophlebitis (6 weeks)												CRITICAL
10	Randomised trial	serious[a]	None	None	Very serious[c]	none	45/200 (22.5%)	135/200 (67.5%)	RR 0.33 (0.01 to 7.62)	42 fewer per 1000 (from 62 fewer to 414 more)	VERY LOW	HIGH

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Overall grading

GRADE	DEFINITION
High	Further research is very unlikely to change our confidence in the quality of evidence for the outcome.
Moderate	Further research is likely to have an important impact on our confidence in the quality of evidence for the outcome and this research may change the estimate.
Low	Further research is very likely to have an important impact on our confidence in the quality of evidence for the outcome and is likely to change the estimate.
Very Low	Our confidence in the quality of evidence for this outcome is very low

Questions and Evidence

- Internationally agreed ways of grading evidence
- Often not get evidence of high quality
- How much weight give to lower quality evidence?
- Is it better to make a recommendation than not to make a recommendation?
- Is it better to make a research recommendation?

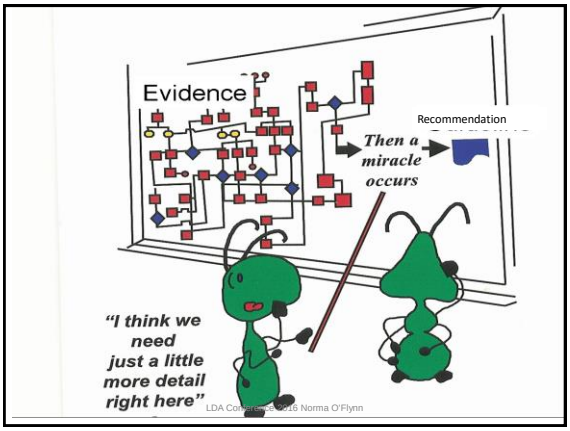
Questions and evidence

- Making recommendations for whole NHS
- Increasing need to look at resource impact
- Recommendations can stifle research
- Use pathways to NIHR to set priority research recommendations

Evidence to recommendations

- Each recommendation has its own linking evidence to recommendations table (LETR)
  - Move from evidence to recommendations in a transparent and logical way
  - Outlines how we have considered the clinical and economic evidence and developed the recommendation

Recommendations	Content
Relative values of different outcomes	
Quality of the clinical [edit or delete the word 'clinical' as appropriate] evidence	
Trade-off between clinical [edit or delete the word 'clinical' as appropriate]benefits and harms	
Trade-off between net health effects and costs	
Other considerations	



NICE guidelines

- Clear process for development
- Objective standard of evidence required
- Prefer evidence to consensus
- Groups usually surprised by lack of good quality evidence or sometimes lack of any evidence!
- Often overturning longstanding beliefs……uncomfortable for everyone

Difficulties

- Level of available evidence
- Not include issues of professionalism or competency

But:

- Research recommendations
- Identify uncertainties, lack of evidence
- NICE partnership with NIHR
- Update process

Confidentiality

- Committee work confidential
- Allows robust discussion between committee
- Evidence often iterative – initial thoughts may change as analysis develops
- Need to consider cost effectiveness

Declarations of interest

- Various categories – financial, personal, specific
- Protect reputation of committee members
- Protect reputation of guideline
- How would others perceive this?

- Declaration of interest will be made public
  - Included in minutes after each meeting and published on web following GC approval of minutes
  - Published in guideline
  - Freedom of information requests

Thank you to my colleagues at NGC for use of slides

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