National Institute for Health and Clinical Excellence

A guide to NICE

Dr David Halpin Consultant Physician & Honorary Senior Clinical Lecturer Chair NICE Guideline Development Goups

National Institute for Health & Clinical Excellence

Part of the NHS

- Established as a Special Health Authority in April 1999 to promote clinical excellence and the effective use of resources within the NHS.
- The functions of the Health Development Agency (HDA), were transferred to NICE in April 2005.
- Guidance mainly affects England & Wales



National Institute for Health & Clinical Excellence

Produces guidance in three areas of health:

- public health guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
- health technologies guidance on the use of new and existing medicines, treatments and procedures within the NHS
- clinical practice guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
 - □ 50 published
 - □ 48 in progress (33 slots & 15 in prep).

National Institute for Health & Clinical Excellence

Funded by Government (Department of Health)

NICE Annual Budget 2007-7 £27.7m (~ \$50m)

Budget for each clinical guideline

NCC staff	£230k	\$460k
GDG meetings	£70k	\$140k
Total	£300k	\$600k

Using NICE Guidance

- No mandatory link to reimbursement
- Department of Health published 'Standards for better health' in 2004: set out how NHS organisations should respond to NICE guidance.
 - Technology appraisals and interventional procedures guidance are 'core' standards (the minimum level of service patients can expect);
 - Clinical guidelines are 'developmental' standards (frameworks for planning improvements in services).
- The Healthcare Commission is responsible for monitoring progress

Funding Implementation of NICE Guidance

Funding Implementation of Recommendations

- NHS organisations in England and Wales required to provide funding for drugs and treatments recommended by NICE in its HTA guidance out of existing budgets within 3 months
- No specific rules for implementation of Clinical Guidelines but

Several different groups suggest topics on which NICE should develop guidance.

- Health professionals, patients, carers and the general public suggest topics on which they think a NICE public health intervention or programme technology appraisal or clinical guideline would be useful.
- The National Horizon Scanning Centre suggests emerging health technologies that might need to be assessed by NICE.
- The Department of Health's National Clinical Directors and policy teams suggest topics.

NICE reviews each of the suggestions received to ensure they are appropriate and to check whether they are already included in its work.

The suggestions are then filtered according to a check list based on the Department of Health's selection criteria which take account of

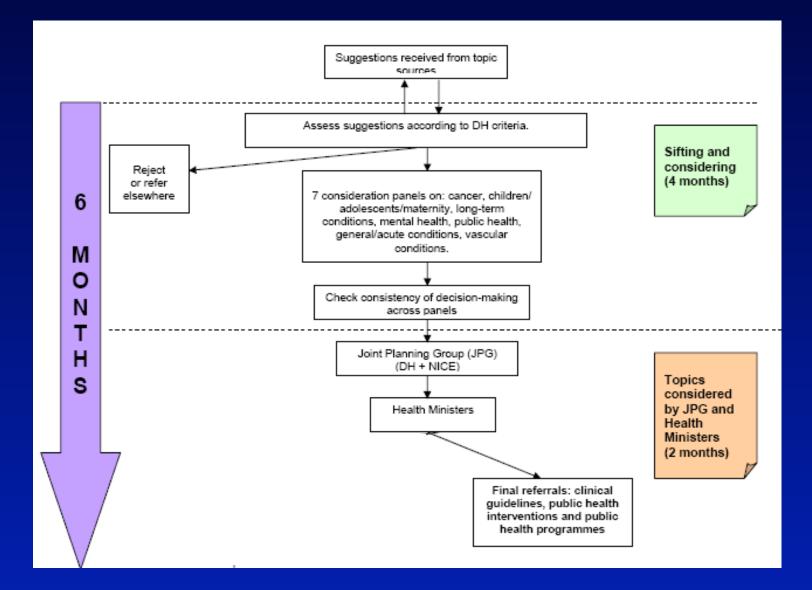
- Burden of disease (population affected, morbidity, mortality)
- Resource impact (i.e. the cost impact on the NHS or the public sector)
- Policy importance (i.e. whether the topic falls within a government priority area)
- Whether there is inappropriate variation in practice across the country
- Factors affecting the timeliness or urgency for guidance

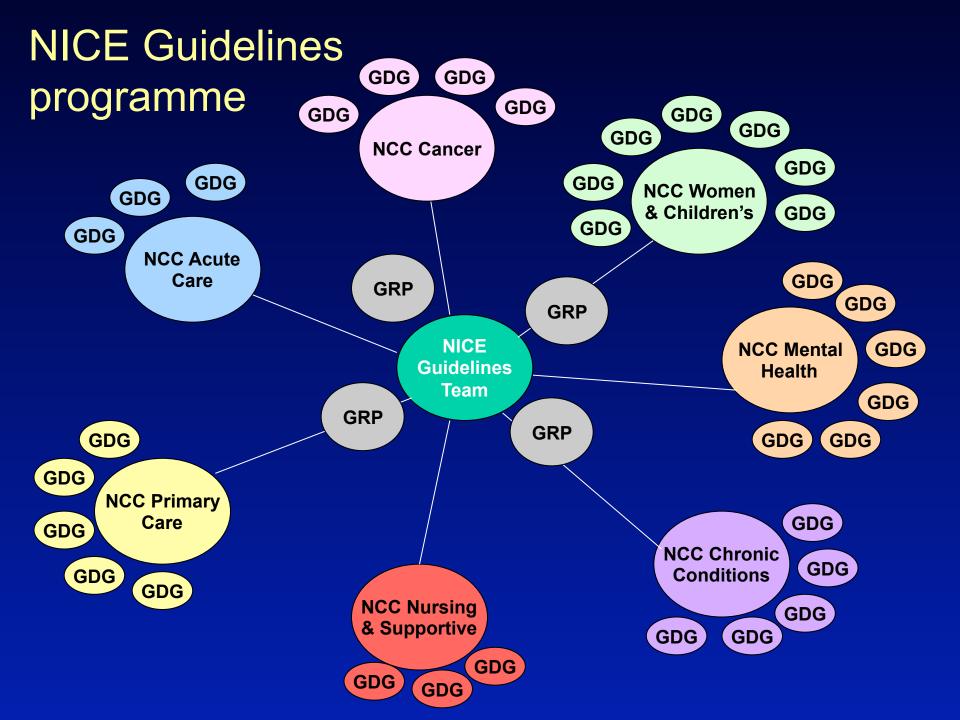
The suggestions are then reviewed by consideration panels composed of

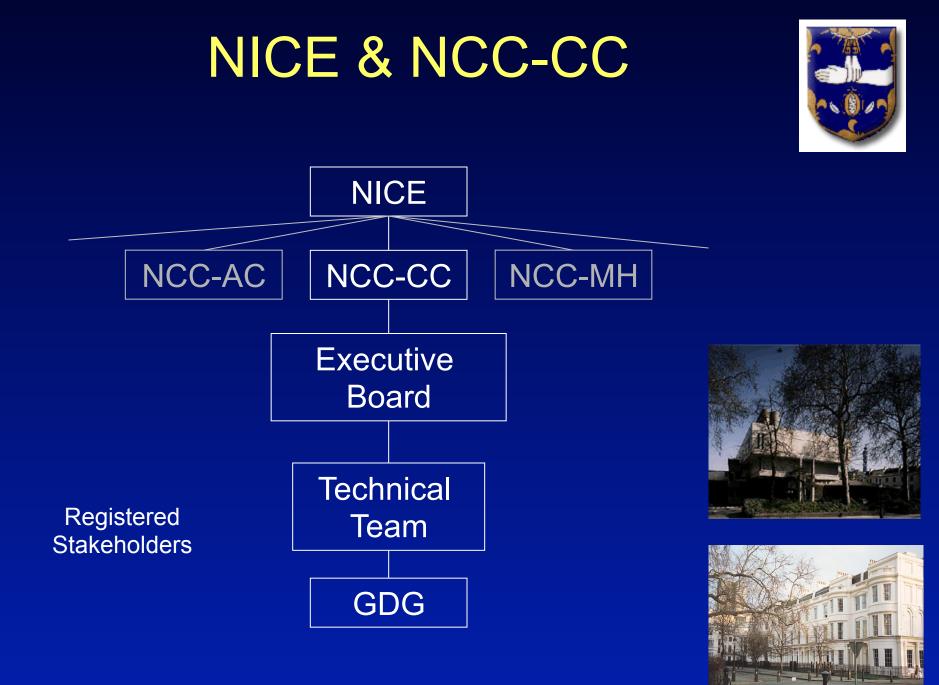
- experts in the topic area
- generalists with a good knowledge of the health service
- public health and the public sector
- patient and carer representatives.

The panels' recommendations go to the Department of Health

A health Minister makes the final decision on which topics are referred to NICE for guidance to be produced.







Technical Team

- Chair
- Clinical Expert
- Systematic Reviewer
- Health Economist
- Information Scientist
- Project Manager



Membership of AMCKD GDG

Discipline	Nọ on GDG
Chest medicine	1*
Nephrology	4*
Paediatric Nephrology	1
Care of Elderly	1
Diabetology	1
Haematology	1
Pharmacy	1
Nursing	2
Primary care	1
Patient stakeholders	2
Public health	1
Technical team	4
Total	20

No industry involvement in development process

Selection of Technical Team & AMCKD GDG Members

Chair Clinical Expert

Research Fellow Information Scientist Health Economist Project Manager

GDG Members

Appointed by NCC Board Appointed by NCC Board

Employed by NCC Employed by NCC Employed by NCC Employed by NCC

Nominations invited from Relevant Stakeholder Organisations e.g.: Specialist Societies Royal Colleges

Patient Representatives selected on basis of written application

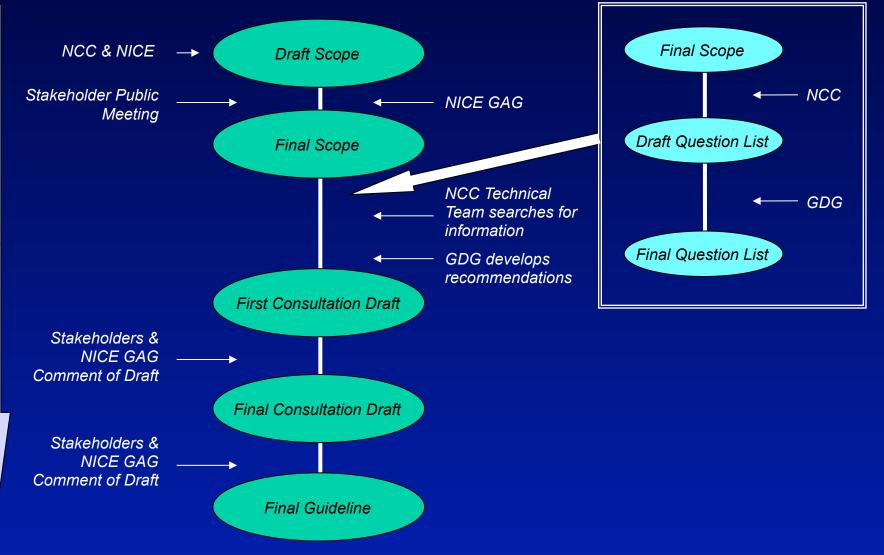
Specialist Societies Nominating GDG Members

Anaemia Nurse Specialist Association British Association for Paediatric Nephrology British Geriatrics Society British Renal Society Cochrane Renal Group Faculty of Public Health Royal College of Pathologists Royal College of Physicians Royal College of Nursing UK Renal Pharmacy Group

Stakeholders

- national patient and carer organisations that directly or indirectly represent the interests of people whose care is covered by the guideline ('patient and carer stakeholders')
- national organisations that represent the healthcare professionals who provide the services described in the guideline ('professional stakeholders')
- companies that manufacture the medicines or devices used in the clinical area covered by the guideline and whose interests may be significantly affected by the guideline ('commercial stakeholders')
- providers and commissioners of health services in England, Wales and Northern Ireland
- statutory organisations including the Department of Health, the Welsh Assembly Government, NHS Quality Improvement Scotland, the Healthcare Commission and the National Patient Safety Agency
- research organisations that have done nationally recognised research in the area.

NICE Guideline Development Process



Writing Recommendations

Technical team	Search for & Appraise Evidence
GDG	Discuss evidence & draft recommendations
Technical team	Refine draft recommendations
GDG	Agree recommendations
Technical team	Search for & Appraise New Evidence
GDG Consensus meeting	Review and agree all recommendations
Stakeholders	Ammend recommendations if necessary
Stakeholders & NICE	Ammend recommendations if necessary

Grading Evidence & Recommendations

Level	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1–	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of biasa
2++	High-quality systematic reviews of case–control or cohort studies
	High-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2–	Case–control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causala
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus

Recommendations are now not graded

The Final Product

NHS National Institute for

Kan Sagan Carport



Four Versions

- Full Guideline
- NICE Version
- Quick reference Guide
- Information for People who use NHS Services

NICE Implementation Strategy

- active engagement with the NHS, local government and the wider community (for example, by encouraging people to suggest topics for NICE guidance and to work with us as we develop guidance)
- directly spreading the word (such as sending quick reference guides for new clinical guidelines directly to the people who put the guidance into practice)
- creating tools to help put guidance into practice (for example, local costing templates for guidelines – available on the NICE website)
- education (for example, engaging with those responsible for undergraduate training programmes)
- monitoring and inspection (such as working with the Healthcare Commission and the Audit Commission to develop methods of monitoring how NICE guidance is put into effect)
- spreading good practice (telling people all over the country about good local work, so that other organisations can copy it).

NICE Implementation Strategy

Once NICE publishes clinical guidance, health professionals and the organisations that employ them are expected to take it fully into account when deciding what treatments to give people. However, NICE guidance does not replace the knowledge and skills of individual health professionals who treat patients; it is still up to them to make decisions about a particular patient in consultation with the patient and/or their guardian or carer when appropriate.

When NICE publishes clinical guidelines, local health organisations should review their management of clinical conditions against the NICE guidelines. This review should consider the resources required to implement the guidelines, the people and processes involved, and how long it will take to do all this. It is in the interests of patients that the NICE recommendations are acted on as quickly as possible.

Barriers to Guideline Implementation



855 General Practice Guidelines in Cambridge Health Authority in 1998



Strengths of NICE Guidelines

- Rigorous methodology
 - Transparent process
 - Open topic selection
 - Inclusive, consultative approach to scope
 - NHS organisations
 - Patients
 - Specialists
 - Industry
 - Independent, professional critical appraisal of evidence
 - Health economic input
 - Governmental funding
 - Editorial independence of GDG
 - Rigorous consultations on drafts
- Guidance is for managers as well as clinicians
- Clinical Guidelines become part of NHS policy in E & W
- Implementation monitored by Healthcare Commission

Weakness of NICE Guidelines

- Slow methodology
- Ability to respond to new evidence
- Size of topic that methodology can address
- No specific funding to support implementation
- Organisation of services to ensure delivery of guidance is outside remit
- Dissemination still somewhat arbitrary

Future Outlook for NICE Guidelines

- Fragmentation of NHS
- Plethora of guidelines
- Guideline updates
- Funding

www.nice.org.uk