NICE GUIDELINES
How are they generated? Why do they matter within and outside the UK?

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Critical Issues - Liverpool

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Confessions

- Past Chair NICE Advisory Committees
  - Interventional Procedures (2002-15)
  - Medical Technologies (2009-15)

- Medicines and Healthcare products Regulatory Agency (MHRA)
  - Non-Executive Director [devices] (2015-21)

- Vascular Surgeon

Why is there concern?

Recent NICE draft AAA guideline:

- "Do not offer EVAR if surgical repair is suitable …. or if they are unfit for surgery"

… out of tune with established current practice, UK and worldwide

Vascular Society considered that the draft

- Gave undue emphasis to just one RCT
- Considered long-term outcomes only
- Focussed on cost-effectiveness

- Failed to take account of patient preferences
- Ignored implementation and training issues
- Used outdated evidence

Examining the AAA controversy

VSGBI made points & said “old data”, so **NICE**

- Put new VS data into its cost model and produced the same conclusions
- Consulted with interested parties
- Sought & introduced additional evidence
- Re-convened the Guideline Committee

…. Watch this space ….

NICE guidance on procedures and devices

Interventional Procedures: Safety & efficacy (not cost)

Technology Appraisals: Clinical & cost effectiveness **– *the only mandatory guidance for the NHS***

Medical Technologies: device/diagnostic adoption

Clinical Guidelines - Managing specific conditions
- Link to **Quality Standards**

NICE guidance on EVAR

Interventional Procedures:

IPG10 – 2003

IPG 163 - 2006

Technology Appraisals: **TA 167 – 2009**

Medical Technologies: **If manufacturer chooses**

Clinical Guidelines: **Current (was due 2018)**

Principles of producing NICE guidance

- Evaluations based on wide range of evidence
  - Published evidence
  - Expert advice
  - Patient experience
  - Other stakeholders
- Independent advisory committees
- Explicit and transparent processes
- Public consultation
- Opportunity for appeal/resolution
- Publication

Different types of NICE committees

Standing Advisory Committees (TA/IP/MT)

- Members/Chair appointed for 3 years (-10 years)
- Wide range of interests/expertise
- Chair not "specialist" (leaves if any possible conflict)

Become very experienced over wide range of topics

Clinical Guideline Committees
(formerly Guideline Development Groups – GDGs)

- All appointed for that guideline topic only
- Chair is a "specialist"

Therefore less experienced

Development of AAA guideline

- Feb 2015 – Topic agreed with DH
- April 2015 – Recruitment of Chair and Members
- June-August 2015 – Drafting scope
- August 2015 – Consultation on scope
- November 2015 – Scope published
- July 2016 Equality impact assessment published
- November 2016 - Pause
- April 2017 – Committee meeting
- **May-June 2018 – Consultation on draft guidance**
- **February 2019 – Additional Committee meeting …**

…. the present situation

- Very unusual
- NICE has all it can get from the Committee
- Significant of external input
- NICE well aware of the controversy

Will the guideline be published …and when?

My observations/inferences when Clinical Guidelines have caused controversy in the past…

- Commonly just one aspect is controversial
- Often about “advances” in practice when clinicians are being slow (e.g. U/S for central lines)
- Chair may be very influential

Why NICE guidelines matter in the UK

Generally accepted as the "gold standard"

- Slow start in early 2000's but
  - Big media attention
  - Close involvement of specialist societies, etc.

- TA recommendations mandatory for the NHS
- Now embedded in NHS & health professions
- "*Awaiting the NICE guideline*" is common
- Expectations of Care Quality Commission
- Influential medicolegally

NICE guidance overseas

- NICE pioneered cost effectiveness (cost per QALY)
- Very many website hits every day (USA etc)
- Manufacturers: "*Approved by NICE*" important worldwide
- Some countries simply use NICE guidance

NICE guidance overseas
- services for other countries

Adaptation

- NICE sells selected content or full guidance
- Adapted, under licence, using ADAPTE etc.
- Combine with other guidance, add local content
- Translated

- NICE does not QA or co-badge

- Clients include: Australia, Canada, Ireland, Germany, Saudi Arabia, South Korea, Spain, Tunisia

NICE guidance overseas
- services for other countries

Contextualisation

- Bespoke service using NICE guideline content for *de novo* guideline development
- Allows new locally-relevant guidance to be produced quite quickly

- NICE advises on scope, GDG, stakeholders, etc.
- Input and review by NICE
- Co-badging permitted

Conclusion

- NICE guidance development - independent, evidence-based, robust, transparent processes
- 95%+ NICE guideline content not controversial
- I think the AAA controversy is due to selective emphasis the Committee has chosen to place on aspects of the available evidence
- A most unusual situation now exists

….Watch this space….