MDT decision-making on complex interventions for patients with advanced life-threatening disease

Some experience and learning from NICE

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Some considerations

- How to balance efficacy and safety?
  - Is efficacy established?
  - Is it safe enough?
- How to balance survival vs QoL?
- How to interpret surrogate data (scans, bloods)?
- How to assess cost and value?
- What about use in research?
- What does the well-informed patient *want*?

NICE Interventional Procedures guidance

- Since 2002 – now 540 IPGs
- Across whole of surgery and medicine

- Is it safe enough? Does it work well enough?
- Consent/information
- Training, expertise, facilities
- Further evidence needed
- Patient selection – usually MDT ……

NICE Interventional Procedures guidance

Experience…….

- MDT is the pivot of patient selection

BUT learning ……..

- Be careful when defining an MDT

- MDTs variable and unpredictable

NICE Interventional Procedures guidance RECOMMENDATIONS

1. Evidence adequate – *"normal arrangements"*

2. Evidence limited - *"special arrangements"* for governance, consent, audit/research

3. *Research only*

4. *Do not use*

NICE Interventional Procedures guidance

- No consideration of cost
- Risk of commissioners saying “No” if “special arrangements” or “research”
- Committee Comments *aim* to steer

NICE IPG examples

IPG56 Sugarbaker technique for pseudomyxoma peritonei (2004)

- No controlled studies
- Big risk of serious AEs & efficacy unclear
- Needs evaluation vs less radical surgery
- Evidence limited – NSCAG centres only

NICE IPG examples

IPG298 Ex-vivo hepatic resection and reimplantation for liver cancer (2009)

- Case series of 24 - 22 with cancer:
- 9 (41%) died during same admission
- 7 (22%) needed donor transplantation
- 10/13 (77%) died of recurrence at 12-36/12

- "Evidence raises concerns" … Special
- Patient selection – usually MDT

- Only for patients who would not survive and no other remaining treatment options

NICE IPG examples

IPG470 Ultra-radical surgery for advanced ovarian cancer (2011)

- Only with special arrangements
- MDT patient selection
- Appropriate expertise – perhaps combined surgical team

- Comment: Balance between any survival advantage and morbidity/QoL

NICE IPG examples

IPG177 Left ventricular devices as bridge to transplantation or recovery (2006)

- Normal arrangements
- Patients must understand high complication rate and that the procedure is temporary measure

- Only refers to patients for whom other treatments would be ineffective, eligible for transplant, or heart failure likely to be reversible
- Excludes destination therapy

NICE IPG examples

IPG482 ECMO for acute heart failure (2014)

- Only with special arrangements
  - Uncertainty which patients will benefit
  - High incidence of serious complications

Comments

- Patient selection fundamental
- *Short term* - so need strategy before using
- Likely to recover or plan for e.g. transplant
- ECMO may need to be withdrawn

NICE IPG examples

IPG421 TAVI (2012)

1. Patients unsuitable for SAVR – ***Normal***

2. Patients suitable for SAVR but high risk – ***Special*** (and consider UK TAVI trial)

3. Patients at low risk for SAVR – ***Research only***

Many have poor prognosis: **consider life expectancy**

For all – ***ENTER INTO UK CCAD***

Data collection, registers, etc.

An endless saga ……

- Ideally for *all* procedures with limited evidence
- Bolsters evidence base
- Good for safety data – adjunct to studies
- Gives information about adoption and where
- Coding system inadequate

- Various strategies
- Ideally integrate into commissioning

Use with evidence development or **Commissioning Through Evaluation**

Examples:

- Selective Internal Radiation Therapy (SIRT) - for primary and secondary liver cancer
- Percutaneous mitral valve leaflet repair (“Mitraclip”)

Use in research only

- Fully justified when real uncertainty
- RCTs can be difficult for these treatments
- Organised data collection is an option

NICE Technology Appraisals guidance

- Is it clinically effective?
- Is it cost effective?

- High impact procedures only
- Dominated by new costly drugs
- Cost per QALY - Cost threshold

NICE Technology Appraisals guidance - example

TA357 Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab (2015)

- Only after progression with ipilimumab and, for V600 mutation +ve, after BRAF/MEK inhibitor
- When company provides drug with agreed discount

- Difference in progression-free survival:
  - Central review - 2.9 vs 2.7 months ($p<0.0001$)
  - Investigator review – 3.7 vs 2.6 months ($p<0.0001$)

- ICER £68K 50% chance cost effective @ £50K

NICE MedTech guidance

Aim – Encourage adoption of new techs

- Benefits to patients
- Benefits to the NHS (cost)

  …. compared against current management
- Cost consequences analysis

- Cannot recommend if “more costly”

MedTech example

MTG9 PleurX peritoneal catheter system for treatment-resistant recurrent ascites (2012)

- Clinically effective; low complication rate; improves QoL
- Allows early and frequent treatment
- In community rather than inpatient

- Estimated cost saving of £679 compared with inpatient large-volume paracentesis

Two final thoughts ……..

Expertise and facilities

- Where is the best place for this complex intervention?
- Are the facilities and support here ideal?
- Is the medical/surgical team ideally composed and experienced?

The fully-informed patient and family

- Difficult – clutching at straws
- Clear explanation of:
  - Magnitude of intervention
  - Risks (death, serious disability)
  - Anticipated effect on QoL
  - Chance of cure
  - Likely progression of disease
- Alternative care – including palliative care