Advanced Therapy Medicinal Products and NICE

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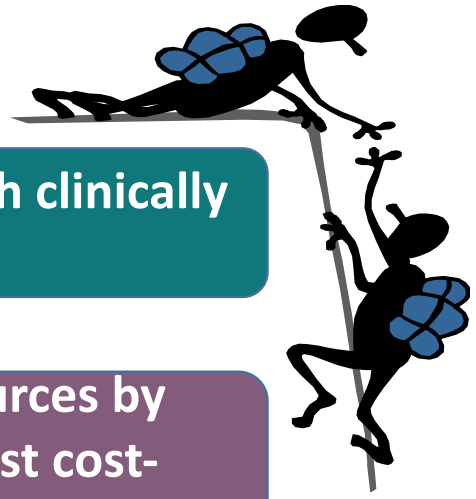
NICE National Institute for Health and Care Excellence

NICE – aims:



Speed up NHS uptake of interventions that are both clinically and cost-effective

Produce evidence-based guidance

Encourage better and more rational use of resources by focussing the provision of healthcare on the most cost-effective interventions

Develop quality standards and performance metrics

Encourage more equitable access to healthcare (reduce post code lottery of care)

Provide a range of information services

Encourage the creation of new and innovative technologies

Changes to NICE Technology Appraisals and Highly Specialised Technologies Programmes

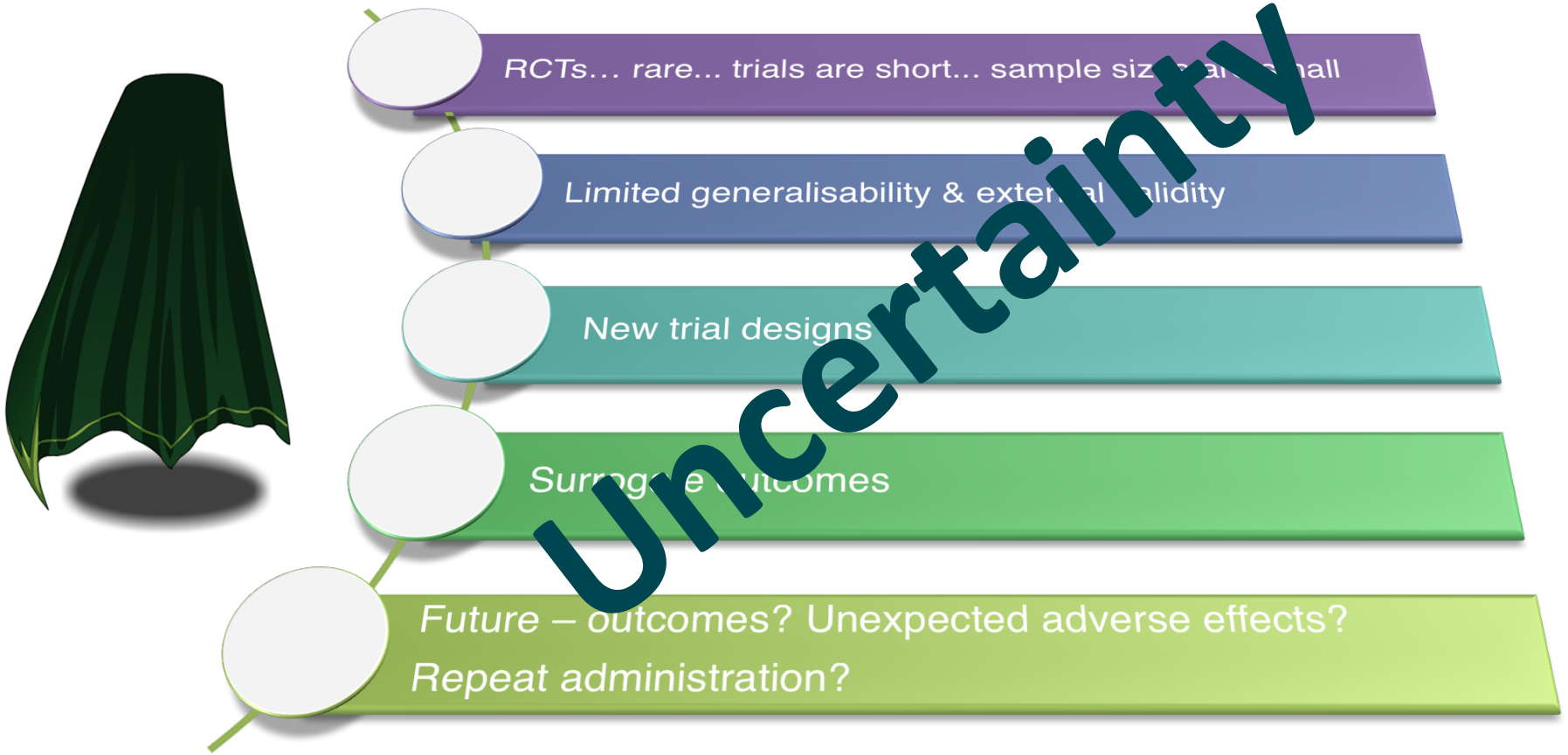
- Important changes were made in 2017 to support financial sustainability
- Budget Impact Test
  - All technologies are subject to a budget impact test
  - Technologies with a budget impact of more than £20m pa in the first 3 years of implementation may be subject to commercial negotiations with NHS England in addition to NICE cost effectiveness analyses
- Cost per QALY threshold introduced in the HST Programme
  - Previously took account of cost per QALY but there was no threshold against which to judge value
  - Thresholds of £100,000 - £300,000 per QALY introduced (applicable threshold depends on the magnitude of individual patient benefit)

NICE Regenerative Medicine Study

- Hypothetical Car-T Cell product
- Study allowed detailed consideration of specific challenges associated with the evaluation of ATMPs including the interplay between evidence maturity, price and payment methods
- Two reports:
  - Detailed technical report produced by the York team
  - Short overview report produced by NICE

https://www.nice.org.uk/about/what-we-do/science-policy-research/nice-research

What about the evidence?



How can the economic risk for ATMPs be reduced?

Two main approaches:

•Cost sharing arrangements:

Or

•Managed Access Agreements (Patient Access Schemes , Managed Entry Schemes or Performance Based Risk Sharing arrangements (PBRSA))

Can be linked to Health Technology Assessment (HTA)

The picture so far…

- Chondroselect - Autologous chondrocyte implant – ***NO***
- MACI - full thickness cartilage defects of the knee –***NO***
- Autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy (IPG274)
- Provenge (Sipuleucil-T) - metastatic (non-visceral) prostate cancer – ***NO***
- Talimogene laherparepvec (TA410) for treating unresectable metastatic melanoma – ***YES***
- Holoclar (TA467)– ex-vivo autologous corneal epithelial cells containing stem cells – ***YES (optimised)***
- Strimvelis (HST) – combined immunodeficiency caused by adenosine deaminase deficiency – ***going through evaluation consultation now – YES?***

…..and what is coming next

- Alipogene tiparvovec (Glybera) – familial lipoprotein lipase deficiency – HST (block scoping report)
- Chondroselect, MACI and traditional autologous cultured chondrocytes (currently under hospital exemption) – technology appraisal
- Axicabtagene ciloleucel (KTE – C19, CAR-T) for treating relapsed or refractory diffuse large B-cell non-Hodgkin lymphoma – guidance in development
- KTE-C19 for treating relapsed or refractory mantle cell lymphoma - Topic selection
- Tisagenlecleucel-T (Kymriah (CTL019)), for children and young adults with B-cell ALL that is refractory or has relapsed at least twice
- Zalmoxis – genetically modified T cells – immunogene therapy – conditional marketing authorisation

Get in touch…

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