The NHS England Proton Service

EU Commission Sub-Group on Proton Therapy

Luxembourg October 2018

NHS England National Clinical Lead PBT
How did we get here?

- **2007 Cancer Reform Strategy**
  - Clinical Consensus Document
  - Clinical Policies Developed
  - Recommended Treatment Overseas and Explore Business Case UK based centre(s)

- **2008 Proton Overseas Programme**
  - NHS England Highly Specialised Commissioning
  - Scotland NHS National Services

- **2015 FBC - £250M**
  - Department of Health
  - Treasury Approved
  - State of the Art Equipment & Building
  - 1500 Patient Capacity = 1.5% Radical RT

- **2018 Christie Hospital Manchester - Opens**
- **2020 UCLH London - Opens**
Basic Facts

Overseas Programme

• Total Referred into POP
  – Paediatric 918
  – TYA 215
  – Adult 471
  – Total 1604

• Average Paeds / TYA decision time 4 calendar days for approval

• Approval rates 2015-2018

<table>
<thead>
<tr>
<th></th>
<th>Paed</th>
<th>TYA</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>410</td>
<td>142</td>
<td>157</td>
</tr>
<tr>
<td>No</td>
<td>30</td>
<td>9</td>
<td>77</td>
</tr>
<tr>
<td>% Yes</td>
<td>92</td>
<td>94</td>
<td>67</td>
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</tbody>
</table>
Referrals into Proton Overseas Programme by Age
2008-2017

- Paediatric
- TYA
- Adult

NHS England
# Approvals By Diagnosis - Paeds and TYA

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhabdomyosarcoma</td>
<td>219</td>
</tr>
<tr>
<td>Ependymoma</td>
<td>180</td>
</tr>
<tr>
<td>Low Grade Glioma</td>
<td>168</td>
</tr>
<tr>
<td>Ewings</td>
<td>160</td>
</tr>
<tr>
<td>Craniopharyngioma</td>
<td>121</td>
</tr>
<tr>
<td>Chordoma</td>
<td>36</td>
</tr>
<tr>
<td>Soft Tissue Sarcoma</td>
<td>29</td>
</tr>
<tr>
<td>Chondrosarcoma</td>
<td>20</td>
</tr>
<tr>
<td>Nasopharyngeal Carcinoma</td>
<td>12</td>
</tr>
<tr>
<td>Salivary Gland</td>
<td>11</td>
</tr>
<tr>
<td>Retinoblastoma</td>
<td>9</td>
</tr>
<tr>
<td>Osteosarcoma</td>
<td>7</td>
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<tr>
<td>Meningioma</td>
<td>6</td>
</tr>
<tr>
<td>Neuroblastoma</td>
<td>6</td>
</tr>
<tr>
<td>Non-germinomatous germ cell tumour</td>
<td>6</td>
</tr>
<tr>
<td>Pituitary Adenoma</td>
<td>6</td>
</tr>
<tr>
<td>Other Adenoma</td>
<td>20</td>
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</table>
# Approvals By Diagnosis - Adult

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chordoma</td>
<td>169</td>
</tr>
<tr>
<td>Chondrosarcoma</td>
<td>95</td>
</tr>
<tr>
<td>Soft Tissue Sarcoma</td>
<td>12</td>
</tr>
<tr>
<td>Ewings</td>
<td>9</td>
</tr>
<tr>
<td>Adenoid Cystic Carcinoma</td>
<td>4</td>
</tr>
<tr>
<td>Nasophargyngeal Carcinoma</td>
<td>3</td>
</tr>
<tr>
<td>Adult Other</td>
<td>10</td>
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What does good surgery look like? Guidelines

- Quality of Resection
- Quality of Imaging
- Pathway Management
- Quality Standards Resection
- Combined Endoscopic / Lateral Cranial Approach
- Cross-refer to high volume expert skull base unit
Referral Process

• Local Cancer Centre MDT
• Local Patient assessment Radiation Oncology

• Refer through NHS Referral Portal
  – Structured data collection
  – Panel and referral function faster
• Imaging through Image Exchange Portal

• NHS England
• NHS Scotland
• NHS N Ireland
• Wales procurement Process

• National Panels
  – Paeds / TYA
  – Skull Base / CNS
  – Sarcoma
  – Head and Neck

• Clinical Policy criteria
• Safety
• Critical Friend ‘MDT’

• Recommend approval or rejection
• Conditions
Outcomes / Results

- National Dataset Completed
- Vision for Outcomes
- Collections systems
- Funded Analysis
- Sufficient numbers and duration
  - Paediatric overseas - Published
  - Ependymoma – PROS presented
  - Skull Base Chordoma - underway
Protons - Low Energy

- Eyes – Choroidal Melanoma
- Clatterbridge 1989
- First hospital based cyclotron in world
  - 2830 + Patients
- Excellent Results
  - 95% local control
  - 90% preservation of eye
  - 80% preservation sight
- Complex service
- Durability of expensive equipment
Expansion of PBT in UK

- NHS
- Clatterbridge
  - Low Energy - Eyes
- Christie 2018
- UCLH 2020
- Commercial
- Rutherford Centres
  - Newport
  - Northumberland
  - Reading
  - Liverpool
  - London
- AVO
  - London
- Proton Therapy UK - Prague
- Munich
What is missing?

- Conventional Evidence Base
  - Direct Clinical Comparison
  - Randomised Controlled Trials

- Incremental gain adult most common cancers difficult

- Very High cost

<table>
<thead>
<tr>
<th>Cost per case</th>
<th>£40,000</th>
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<tr>
<td>Excess Annual Cost 10% All RT</td>
<td>£540M</td>
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- Size of facilities – even one room

- Incomplete Technical Evolution
Evidence Base - Is this proof?

Merchant et al. IJROBP 90 (3) 2014
Conflict in Assessing Evidence for PBT

Radiotherapy is a Deterministic Based Science?

- Modelling = Treatment Planning
  - Dose
- NTCP - Late effects
- Dose Response Curves
- Radiation Exposure – Integral Dose

Clinical Consensus

Randomised Controlled Trials?
- Direct Clinical Comparison?
- Rapid Evidence Reviews
- Not Systematic Reviews

Insufficient

NHS Clinical Policies
But Uncertainties – Greater and Lesser

- Fractionation?
- Addition of systemic agents?

- Spot Scanning
  - Evidence is with passive scattering

- Range Uncertainty – where does it stop?
- Imaging
- Movement
- Target Volumes different
- Metal work

- Model based approach?

- Re-imaging and Re-planning

- Assumption Protons are better – commercial centres, media and marketing – ‘No side Effects’

- ‘Dose planning studies without robust evaluation and optimisation are little more than a beauty pageant’

- CTRad PBT Trials Strategy Group
  - David Sebag-Montefiore

- Myth Busting
- Patient Groups and Equipoise

- Photon RT Improving

- RBE
• Strict Higher Priority = where dose distribution suggests could address problem or limitation in conventional RT?

• Accept Consensus and Higher principles ’Physics’ where overwhelming

• Resist Commercial Model ahead of evidence base

• Create evidence base for future

• Open to collaboration - International Studies

• Cost-Effectiveness assessment AFTER studies assessing clinical gain
Pragmatic Solution

• ‘Routine Commissioning’

• Overwhelming Opinion of benefit and dose distribution
  – Paediatric and TYA
  – Adult Skull Base
  – Adult Spinal Sarcoma
  – Adult Craniospinal

• Trials
  – TORPEDO (oropharynx)
  – L Breast – IMC
  – Mediastinal Lymphoma
  – ABC07 IHCC
  – Anal Cancer
  – Lung – NSCLC
  – Oesophagus

• Evaluative Commissioning
  – Liver - HCC
  – Advanced Nasopharynx
  – Re-Irradiation
  – Common Cancers - TYA

R-IDEAL: A Framework for Systematic Clinical Evaluation of Technical Innovations in Radiation Oncology

Helena M. Verkooijen¹, Linda G. W. Kerkmeijer¹, Clifton D. Fuller², Robbert Huddart³, Corinne Faivre-Finn⁴, Marcel Verheij⁵, Stella Mook⁶, Arjun Sahgal⁷, Emma Hall⁸ and Chris Schultz⁹ on behalf of The MR-Linac Consortium

Frontiers in Oncology 2017
The NHS model for Protons

- Academic High Quality Framework
- Integrated Major Cancer Centre Hospital Environment
- All patients in Prospective Studies / Trials
- Routine Formal Evaluation of Outcomes and Late Effects Treatment
- Technical developments and underpinning translational research
- This strategy can allow the future role of protons to be developed in the UK, based on sound clinical evidence, in a safe, sustainable and affordable way.